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Guidance for the Reregistration of Pesticide Products Containing Rotenone as the Active Ingredient

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS CONTAINING ROTENONE AND ASSOCIATED RESINS AS THE ACTIVE INGREDIENT

OPP Chemical No. 071003, 071004 and 071001

CASE NO. 0255

CAS (DOCKET) NUMBER: 83-79-4

October 1988

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460

United States
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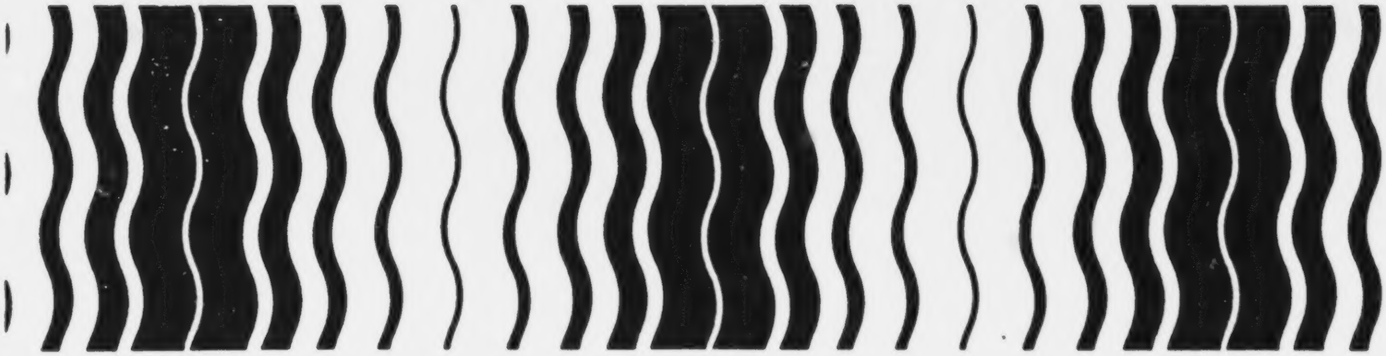
Guidance for the Reregistration of Pesticide Products Containing ROTENONE as the Active Ingredient



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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	active ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
LC50	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD50	Median lethal dose - a statistically derived single dose than can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
MP	Manufacturing Use Product
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs

OES	Office of Endangered Species, U.S. Fish and Wildlife Service
PADI	Provisional Acceptable Daily Intake
ppm	parts per million
RfD	Reference Dose
TMRC	Theoretical Maximal Residue Contribution

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews and Compendium of Acceptable Uses may be obtained from the OPP Public Docket. Write to OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, D.C. 20460

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submission of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of Chemical

The following chemical is covered by this Registration Standard:

Common name: Rotenone (and "other cube' resins" or "other cube' extractives" or "other derris resins" or "other derris extractives")

Chemical name: (2R, 6aS, 12aS)-1,2,6,6a,12,12a-hexahydro-2-isopropenyl-8,9-dimethoxychromeno[3,4-b]furo [2,3-h]chromen-6-one.

Other chemical nomenclature: (R)-1,2-dihydro-8,9-dimethoxy-2-(1-methylethenyl)[1]benzopyrano[3,4-b]furo[2,3-h][1] benzopyran-6,12-dione (9th Collective Index); 1,2,12,12a alpha-tetrahydro-2a-isopropenyl-8,9-dimethoxy[1] benzopyranol[3,4-b]furo[2,3-h][1]benzopyran-6(6aH)-one (8th Collective Index); 1,2,12,12a-tetrahydro-8,9-dimethoxy-2-(1-methylethenyl)-1[2R-(2a,6a,alpha,12a alpha)]-(1)benzopyrano (3,4-b)furo(2,3-h)-(1)benzopyran-6(6aH)-one.

Other names: aker-root; Chem Fish; Derris; derris root; Nicouline; Rotacide; Protex; Tubatoxin; tuba-root; ENT-133; Barbasco; Cube; Haiari; Nekos; and Timbo

CAS Registry Number: 83-79-4

EPA Pesticide Chemical Code (Shaughnessy Number): 71003 - rotenone; 71004 - cube' resins other than rotenone; 71001 - derris resins

Empirical Formula: $C_{23}H_{22}O_6$

Molecular Weight: 394.4

Chemical/Physical Characteristics of Rotenone (purity 99.5% or unspecified) and its associated resins:

Color: colorless (rotenone, purity 99.5%)

Physical State: Crystalline solid

Specific Gravity: 1.27 at 20 °C

Melting Point: 165-166 °C

Solubility: Water 0.00002 g/100 ml at 20 °C; Ethyl alcohol 0.2 g/100 ml at 20 °C; Carbon tetrachloride 0.6 g/100 ml at 20°C; Amyl acetate 1.6 g/100 ml at 20°C; Xylene 3.4 g/100 ml at 20 °C; Ethylene dichloride 33.0 g/100 ml at 20 °C; Chloroform 47.2 g/100 ml at 20 °C; Acetone 6.6 g/100 ml at 20 °C; Benzene 8.0 g/100 ml at 20 °C; Chlorobenzene 13.5 g/100 ml at 20°C.

Stability: Decomposes rapidly in organic solvents exposed to light and air.

Rotenone is a botanical insecticide/acaricide/piscicide derived from roots of Derris spp., Lonchocarpus spp., and Tephrosia spp. primarily from Malaya, South America and East Africa, respectively. It also occurrs in many other related species of legumes growing mostly in the tropics of South America, Pacific islands, Australia, Asia and Africa. Tephrosia virginiana grows as far north as Wisconsin and was used by the Indians as a fish poison in what is now southern and southwestern United States.

In some species, rotenone is concentrated in the leaves, seeds and bark rather than the roots. The concentration of rotenone and associated resins varies considerably depending upon species, plant parts examined, geographic location and climate. Selected varieties of Lonchocarpus utilus roots may contain as much as 12% rotenone and 25% total extractives.

Crushed roots or other plant parts containing rotenone were used in the tropics primarily as piscicides to obtain fish for food. Extracts from Derris spp. have been used as an ingredient in arrow poisons in Sumatra. The earliest record of crop use was in Malaya in 1848.

In 1985 54% of the rotenone used domestically was put to general use including home gardens, livestock, pet, and household use, 32% was used to kill fish and 14% was applied to commercial crops, primarily on potatoes, tomatoes, pears, and apples.

B. Regulatory History

Rotenone or derris or cube root, when applied on growing crops, is currently exempt from the requirement of tolerances (40 CFR 180.1001(b)(8)).

In May, 1980 rotenone was originally included with 44 other chemicals on a list of chemicals considered for special review because of questions regarding acute toxicity to aquatic organisms, non-target wildlife population reductions, hazard to endangered species, and possible oncogenicity, mutagenicity, teratogenicity reproductive, and other chronic effects. The following conclusions were reached.

Rotenone products registered for use as piscicides have a high enough toxicity to fish to exceed special review criterion, which was designed to protect against unintended adverse effects to wildlife. However the Agency decided that " A pesticide should not be presumed against because it performs its intended effect by preventing, destoying, controlling, or mitigating target organisms". Since toxicity of rotenone to fish is considered an intended effect, the provision of 40 CFR 162.11 (a)(3)(i)(B)(3) should not be invoked against rotenone by reason of this acute toxicity to fish.

Rotenone treatments appear to cause temporary reductions in overall invertebrate populations replenished with time by migration into the treated areas and by the gradual re-population by survivors. The treatments can cause a permanent local loss of certain species or genera of invertebrates, particularly aquatic invertebrates. Whether or not this shift in a local or regional pattern of species would significantly affect other ecological balances could not be determined from available data. Hazards to endangered species can be effectively prevented by requiring each proposed treatment site to be evaluated by state or federal fish and wildlife biologists as already required by label statements.

The Agency concluded that the available data did not show that the criterion for oncogenicity (40 CFR 162.11 (a)(3)(ii)(A) was met or exceeded for rotenone and its related compounds.

The data available were not sufficient to show that the criterion of 40 CFR 162.11 (a)(3)(ii)(A) with respect to reproductive effects was met or exceeded for rotenone and its related compounds. However there was sufficient cause for concern to support a requirement for additional testing.

The chronic feeding data available were not sufficient to show that the RPAR criterion 40 CFR 162.11 (a)(3)(ii)(A) with respect to chronic effects was met or exceeded for rotenone in its various forms.

Three conclusions were reached regarding the establishment of tolerances for rotenone. First, tolerances should be established for food and feed crops. Second, even though tolerances cannot be enforced in produce from home gardens, the Agency should re-examine the recommended pre-harvest interval based on plant metabolism and residue data which the Agency should require. Third, because there are several means by which the aquatic uses of rotenone can result in residues in edible fish, the aquatic use will be considered a "food use",and rotenone's aquatic use will require a tolerance or tolerance exemption.

In a Federal Register Notice published July 15, 1981 it was concluded that available data did not indicate that rotenone presented a risk of unreasonable adverse effects to man or the environment. The Agency therefore removed rotenone from its list of suspect chemicals.

A Data Call-In Notice for rotenone issued May 28, 1986 required data for product chemistry of rotenone manufacturing-use products. The Agency required submission of product identity and composition data for brittle extract of cube', technical rotenone, crystalline rotenone, and powdered cube' root. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted.

C. Use Profile

Type of Pesticide: Insecticide, acaricide and piscicide
Year of Initial Registration: 1947
Pests Controlled: Undesirable fish. Number of diverse insect pests attacking field crops, vegetables, fruits, ornamentals, livestock, and pets
Registered Uses:

Terrestrial Food Crops: Rotenone , cube' resins other than rotenone , and derris resins are registered for foliar preharvest applications to vegetables, field crops, tree fruit, and nuts.

In addition to foliar applications, delayed dormant applications may be made to tree fruit.

Soil applications may be made to vegetables,berries and nuts.

Terrestrial Nonfood Crop: Ornamentals, turf, shade trees, and tobacco.

Greenhouse Food Crop: Vegetables.

Greenhouse Nonfood: Ornamentals.

Aquatic Non-Crop: Fish.
Domesticated Pets and Their Man-made Premises: Cats and Dogs.

Livestock: Cattle (Beef and Dairy), Goats, Horses, Sheep, and Swine.

Household: Flying and crawling insects.

Commercial and Industrial Uses: Flying and crawling insects.

Methods of Application: Foliar application by ground and aerial equipment, soil application by ground equipment, hand and mechanical spraying and dusting, dip treatment, shampoos, ear drops, boat bailers, and mothproofing.

Annual Usage: 50,000 to 120,000 lb

Predominant Usage: Aquatic (piscicide); agriculture (potatoes, tomatoes, pears, apples); livestock, pets, and household.

Mode of Activity: Interference in cellular energy reproduction through an inhibition of oxidative phosphorylation - the phosphorylation of adenosine diphosphate (ADP) to adenosine triphosphate (ATP).

Manufacturing Use products: There are 43 manufacturing use products which contain from 0.045% to 50% rotenone.

Formulations: Technicals, formulation intermediates, dusts, pelleted/tableted, wettable powders, wettable powder/dusts, impregnated material, emulsifible concentrates, soluble concentrate/liquids, ready-to-use, pressurized liquids.

Basic Producers: Penick-Bio UCLAF Corporation, Prentiss Drug and Chemical Company, TIFA, Ltd., Fairfield American Corporation

Number of Registrants: 176

Number of Registration: 465; 43 of these products are Manufacturing-Use Products

III. AGENCY ASSESSMENT

A. SUMMARY

The Agency has reviewed all data in Agency files as of December 1987 supporting the registration of rotenone. Based on the available data, EPA has reached the following conclusions. The points summarized below are presented in further detail, in the context of EPA's science findings and additional data requirements, sections B through D.

1. The Agency has categorized rotenone as a Category E carcinogen (no evidence of carcinogenicity).

2. Rotenone is highly toxic to fish and moderately to highly toxic to freshwater invertebrates. Based on available data, it is slightly toxic to birds.

3. Based on acute oral toxicity to rats, rotenone technical and manufacturing concentrates are classified in Toxicity Category I.

4. The Agency believes that the existing exemption from tolerance for rotenone is not warranted and will require the establishment of finite tolerances. Residue data on commercial crops, fish killed by water treatment, and fish used to restock treated bodies of water must be submitted before appropriate tolerances or exemptions from tolerances can be established.

5. Rotenone is unlikely to leach to ground water because of its short half-life in soil and water and low mobility in soils containing more than 1% organic matter. Also, because of its short half-life the potential for runoff into surface waters is low.

6. During the past 10 years, California reported 5 illnesses related to rotenone exposure. All 5 were applicator exposures: 2 were poisonings, 2 were skin injuries, and 1 was an eye injury.

B. OTHER SCIENCE FINDINGS

1. Environmental Fate Profile.

The environmental fate data base for rotenone is incomplete. The available information indicates that it rapidly degrades in water and soil. Except for the piscicide use, there is a low potential for environmental exposure. Rotenone degrades very rapidly under both aerobic aquatic and anaerobic aquatic soil conditions, with a half-life of 1 to 3 days. The major degradate is rotenolone with a half-life of <3 days under aerobic aquatic conditions and 10 weeks under anaerobic aquatic conditions.

The short soil half-life reduces the potential for runoff into surface waters from crop uses. Available studies indicate that rotenone is mobile only in sand sediment containing ≤1% organic matter. It is not very mobile in loam sediment, silt loam sediment, and loamy sand sediment.

Rotenone's potential to leach to ground water is low because of its short soil half-life (less than 3 days), short hydrolysis half-life, and extremely low aqueous solubility (0.00002 g/100 ml). A hydrolysis study indicated that rotenone has a half-life of 13 days (pH 5), 3 days (pH 7), and 2 days (pH 9) in water, with the major degradate being identified as rotenolone. Rotenolone has a half-life of <2 weeks in water.

2. Toxicology Profile

a. Acute Toxicity

1. Acute Oral Toxicity

A study with purified rotenone indicated that the pesticide is classified inn Toxicity Category I because of its high toxicity (LD_{50} = 39.5 ± 2.21 mg/kg for female rats and 102 ± 12.6 mg/kg for male rats).

2. Acute Dermal Toxicity

No date were available for review. An acute dermal toxicity study with technical grade rotenone is required.

3. Acute Inhalation Toxicity

No data are available on the acute inhalation toxicity of technical grade rotenone. A study is required if the technical grade material is in a respirable form.

4. Eye Irritation

No data onn the eye irritation potential of technical grade rotenone were available. A study is required.

5. Dermal Irritation

No data on the skin irritation potential of technical grade rotenone were available. A study is required.

6. Dermal Sensitization

No data on the dermal sensitization potential of technical grade rotenone were available. A study is required.

b. Subchronic Testing

1. Subchronic Oral Toxicity - Rodents

There were no acceptable subchronic toxicity studies available. However, long-term studies with rats and mice are considered below. No additional subchronic toxicity testing is required.

2. Subchronic Oral Toxicity - Non-Rodents

There were no acceptable subchronic toxicity studies available. However, a 6-month study with dogs is considered below. No additional subchronic toxicity testing is required.

3. 21-Day Dermal Toxicity

No data are available, and a study is required.

4. Chronic Toxicity - Dogs

Groups of 6 male and 6 female dogs were given 0, 0.4, 2, or 10 mg/kg/day by capsule for 6 months. A No-observed-effect-level (NOEL) of 0.4 mg/kg/day was established in this study. The lowest effect level (LEL) was 2 mg/kg/day, and dose-related effects included emesis and decreased body weight. The highest dose tested was 10 mg/kg/day and was associated with decreased hematocrit and hemoglobin, serum glucose, cholesterol, and total lipid levels.

5. Chronic Toxicity - Rats

Fischer 344 rats were fed diets containing 0, 7.5, 37.5, or 75 ppm rotenone for 2 years.

Those rats given the mid- and high-dose levels had significantly reduced terminal body weights. Food consumption for the mid- and high-dose group females was significantly reduced in comparison to that for the control group females.

Lower total protein and albumin levels in females given the 75 ppm diet and higher serum urea nitrogen levels in 37.5 and 75 ppm dose group females were observed. These changes were small and are believed to be associated with reduced food consumption.

The only treatment-related macroscopic finding was thin female rats in the 37.5- and 75-ppm dose groups. The 75 ppm diet was associated with an increased incidence of angiectasis and hemorraging in the adrenals of males and females, and reduced incidences of chronic progressive kidney damage (females only), liver degeneration, pituitary adenomas, and mononuclear cell leukemia.

The low effect level (LEL) for decreased body weight and food consumption was 37.5 ppm, and the NOEL was 7.5 ppm (0.375 mg/kg/day).

Since no microscopic examinations were performed on low and mid-dose group rats, a NOEL for the adrenal gland lesions could not be established. Histopathology for the low and mid-dose groups must be submitted to fully evaluate the study.

c. Carcinogenicity

1. Rats

Rotenone was given to groups of 50 male and 50 female F344/N (Fisher 344) strain rats at dietary concentrations of 0, 38, or 75 ppm for 2 years. A statistically insignificant increase in the incidence of parathyroid adenomas in male rats given the 75 ppm diety was noted (4/44 in the high-dose group compared with 1/41 in the control group).

The incidences of pituitary adenomas and mononuclear cell leukemias were significantly decreased in both sexes in the chronic feeding with Fisher 344 rats given dietary levels of 0, 7.5, 37.5, or 75 ppm rotenone for 2 years and no parathyroid adenomas were observed in males given the 75 ppm diet. Increased incidence of other tumors was not observed in treated rats.

2. Mice

Rotenone was given to groups of 50 male and 50 female B6C3F1 strain mice at dietary concentrations of 0, 600, or 1200 ppm for 2 years. A dose-rated decrease in mortality for treated males was noted, but no significant effect on mortality in treated female mice was observed. There was no evidence that rotenone was carcinogenic in male or female B6C3F1 mice.

3. Hamsters

In an 18 month study in the Syrian Golden Hamster, rotenone was fed in the diet at doses up to 1000 ppm. The study was judged inadequate because of poor survival and incomplete reporting of results.

Based on the negative studies in rats and mice, rotenone has been categorized as a Category E carcinogen (no evidence of carcinogenicity). No further studies are required.

d. Developmental Toxicity and Teratology Studies

1. Rats

Groups of 25 pregnant rats were given doses of 0, 0.75, 1.5, 3 or 6 mg/kg/day on gestation days 6 through 19. Decreased body weight and body weight gain were observed in pregnant rats given daily doses of 6 mg/kg/day. The NOEL for these effects was 3 mg/kg, and there were no effects observed at the 1.5 or 0.75 mg/kg dose levels. The 6 mg/kg dose also caused a reduction in mean fetal weight below that of controls, and an increased incidence of unossified sternebrae, renal cavitation, and distended ureters. The adult-to-developmental toxicity (A:D) ratio (the ratio of the NOEL for adult toxicity and the NOEL for developmental toxicity) is equal to one. Thus, rotenone is not teratogenic or fetotoxic to rats at doses lower than those which also cause maternal toxicity.

2. Mice

Dosages of 3, 9, and 15 mg/kg/day were administered to groups of 30 female mice on days 5 through 17 of gestation. Results of the main study suggested a NOEL for maternal and fetal effects that may be higher than 15 mg/kg/day. No dose-related effects were observed at any dose level, suggesting that the NOEL for maternal and fetal toxicity is greater than 15 mg/kg/day. The results of this study were interpreted together with those from a preliminary range finding study. On that basis, the NOEL for maternal effects (weight loss and mortality) and fetal effects (decreased litter size) in mice is 15 mg/kg/day. The LEL is 24 mg/kg/day. The A:D ratio is equal to one. Rotenone is not teratogenic or fetotoxic at doses lower than those which also cause maternal toxicity.

e. Reproduction Toxicity

Rotenone had no effects on reproduction in groups of 15 male and 25 female rats given dietary levels of 0, 7.5, 37.5, or 75 ppm. The LEL with respect to decreased body weight gain in dams and in pups during lactation was 37.5 ppm. Litter sizes in the F_0 and F_{1A} generations were significantly reduced at 75 ppm, and the reproductive NOEL was 37.5 ppm. The NOEL for maternal toxicity was 7.5 ppm (approximately 0.375 mg/kg/day). No additional data on reproductive effects are required.

f. Mutagenicity

1. Gene Mutation

Rotenone did not induce gene mutations in *Salmonella typhimurium* with or without metabolic activation or in yeast. However, concentrations of 0.25 to 4.0 ug/ml rotenone without metabolic activation increased the frequency of forward mutations at the Tk locus of L5178Y mouse lymphoma cells *in vitro*.

Mice given 0.05, 0.17, 0.5, or 1.0 mg rotenone per kg body weight on days 8 through 11 of gestation did not show signs of toxicity or somatic mutations in embryonic melanocytes. A dose of 1000 mg/kg administered to pregnant mice under the same conditions caused melanocyte toxicity, but did not cause somatic mutations.

2. Structural Chromosomal Aberration

Single oral doses of 0.7, 2.5, or 7 mg/kg did not increase the incidence of chromosomal aberrations or decrease the mitotic index in bone marrow cells of treated rats. No increase in the incidence of polychromatic erythrocytes with micronuclei was observed in bone marrow of mice 6 hours after the last of 2 consecutive daily doses of 0, 10, or 80 mg/kg.

3. Other Genotoxicity

No mitotic recombination or mitotic gene conversion was observed in yeast at dose levels up to 10,000 ug/mL.

g. Metabolism

The major route of excretion of rotenone (95 to 97% of the administered dose) is in the feces. Intravenous dosing results indicated that enterohepatic circulation is possible in treated rats, and the route of administration, dose level, and number of doses had no apparent effect on the excretion pattern. Most of the metabolites in the feces could not be identified.

3. ECOLOGICAL EFFECTS

a. Toxicity to Birds

Rotenone is slightly toxic to pheasants and practically non-toxic to mallards. The LD_{50} of rotenone to mallard ducks is 2200 mg/kg and the LD_{50} of rotenone to pheasants is 1680 mg/kg based on studies using 32.38% rotenone. Additional studies using technical rotenone and giving procedural detail are needed No subacute dietary studies or reproduction studies were available for review. These studies are required.

b. Toxicity to Fish

Acceptable acute toxicity data show that rotenone is very highly toxic to rainbow trout (LC_{50} = 22.5 ug/l), channel catfish (LC_{50} = 2.6-2.8 ug/l), and bluegill (LC_{50} = 22.5 ug/l).

In fish accumulation studies in which fish were introduced to water 30 days after treatment, the maximum accumulation in largemouth bass occurred six days after stocking. Bioaccumulation factors were 22x (0.44 ppm) for inedible tissues and 61x (1.22 ppm) in edible tissues. Rotenone concentrations in fish in warmwater ponds were much lower. The maximum rotenone concentration found in bullheads and bluegills were 0.153 ppm in the edible tissues and 0.096 ppm in the inedible tissues. In a laboratory study, radiolabelled rotenone residues accumulated in bluegill sunfish with bioaccumulation factors of up to 3,607x (23.47 ppm)in the viscera but 137x (0.693 ppm) in the carcass. After 21 days depuration the residue levels fell to 0.221 ppm in the viscera and 0.083 ppm in the carcass.

c. Toxicity To Freshwater Invertebrates

Technical rotenone is moderately to very highly toxic to freshwater invertebrates. The 21-day EC_{50} for *Daphnia magna* is 2.1 ug/l. The NOEL is 1.25 ug/l. An aquatic mesocosm study for invertebrates is required for landlocked aquatic environments typical of rotenone's use as a piscicide.

d. Effects on Estuarine and Marine Organisms

No studies using technical rotenone were available for review. Piscicide uses of rotenone are of minimum concern for estuarine organisms because its use is usually restricted to landlocked target fish populations in ponds, reservoirs, and lakes. The agricultural uses are of greater concern because registered pear, apple, tomato, and potato crop uses occur in coastal States. There is insufficient information on usage and acreage on these particular crops to determine effects on estuarine and marine organisms. The rapid degradation and mobility characteristics of rotenone limit the potential for runoff. However, the close proximity of cranberries to the estuarine environment leads to concerns about estuarine organisms.

Additional mollusk testing (e. g. oyster embryo-larvae) is required in order to further evaluate the hazards to freshwater mussels. Testing using oyster larvae will allow the Agency to assess the risks to endangered freshwater mussels from use of rotenone.

C. TOLERANCE REASSESSMENT

1. Tolerances Issued

Currently, use of rotenone or derris or cube root on growing crops or on livestock in the United States is exempt from the requirement of tolerances (40 CFR 180.1001(b)(8). Canadian tolerances of 0.1 ppm (negligible residue) have been established for a variety of vegetable and fruit commodities and also for poultry and red meat including fat and meat byproducts. There are no Mexican tolerances or Codex Maximum Residue Levels established.

Date requirements regarding the magnitude of residues in raw agricultural commodities, plant and animal products, including fish, shellfish, and foods present in treated food handling establishments, will not be determined until all required data regarding metabolism in animals and magnitude of residue in feed items have been received. Upon receipt of the data required under this standard, the tolerance exemption will be reevaluated.

Under present EPA policy, the Agency does not establish tolerances for pesticides in potable water (47 FR 56137; December 15, 1982). No acceptable residue level in drinking water (ARLDW) has been set.

2. Metabolism Studies - Identity of Metabolites in Plants and Animals

The nature of the residues of rotenone in plants and in animals is not adequately understood. Metabolism studies on plants and animals are needed.

3. Residue Analytical Methods

Methods for determination of rotenone residues in plant commodities and for enforcement are not available. Currently, use of rotenone on growing crops is exempt from the requirement of tolerances.

The HPLC method of Dawson and Allen is useful for determination of rotenone residues in water, fish, crayfish, and freshwater clams, but is inadequate for purposes of data collection because complete validation data (sensitivity, accuracy, and precision) were not presented for each commodity.

A spectrophotometric method developed by Jacobsen *et al.* appears adequate for determination of rotenone residues in milk but not in cream because no data were presented for control samples, fortification levels were not specified, and reported recovery values were unacceptably low (17-51%).

4. Storage Stability Data

The available data indicate that rotenone is stable in crayfish, clams and fish muscle, and offal during storage at -10 °C for up to 6 months. Data are not available depicting residue stability in plant or livestock matrices. Such data are required.

The nature of the residue in plants and animals has not been adequately described. If the requested plant metabolism data indicate the presence of additional metabolites of concern, data depicting the stability of those residues during storage will be required. Upon receipt of the requested animal metabolism data, the need for storage stability data pertaining to rotenone residues of concern in livestock tissues will be determined.

5. Residues In Plants

Rotenone has been exempted from the requirement of tolerences and no residue data have been required depicting rotenone residues in or on plant commodities. These data are now being required. Since there are no data, recommendations for the establishment of crop group tolerances are not possible at this time.

6. Residues In Animals

The nature of the residue in animals is not adequately understood. Data requirements regarding the magnitude of the residues in animal products will not be determined until all requested data regarding metabolism in animals and magnitude of residue in feed items have been received.

7. Residues In Fish And Shellfish

The nature of the residue in fish and shellfish is not adequately understood. The available residue data indicate that rotenone residues will be present in fish and shellfish following registered use of rotenone. In a radiolabeled study 46% of the ^{14}C-residues present in bluegill carcasses (presumed to include flesh and skin) were unidentified; metabolism data pertaining to shellfish were not submitted. Additional data are required on the metabolism of rotenone and magnitude of the residue in fish.

8. Residues in Potable and Irrigation Water

The available residue data indicate that residues of rotenone in water on the day of treatment with a 5% EC formulation at 0.25 ppm may be as high as 0.245 ppm.

9. Food Monitoring Data

FDA and USDA do not monitor rotenone as part of the National Residue Program. Domestic and import samples collected by FDA from 1978 through 1987 and the Total Diet Samples collected from April 1982 to April 1986 were not analyzed by methods known to determine rotenone.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS

Based on review and evaluation of all available data and other relevant information on rotenone, the Agency has made the following determinations.

1. The Agency is not placing rotenone in Special Review.

Rationale: None of the criteria of 40 CFR 154.7 for initiating Special Review has been met.

2. The Agency is classifying products bearing piscicide and cranberry uses for restricted use. In addition, a label statement requiring consultation with a state or federal fish and wildlife biologist before aquatic application is specified, to verify that the application will not adversely affect endangered species.

Rationale: Rotenone is very highly toxic to fish and other aquatic organisms. The requirement to consult with a state or federal fish and wildlife biologist will assure that unreasonable risks to endangered species will be avoided. The restriction applies to the piscicide uses, and to cranberry uses because cranberry bogs are periodically flooded.

3. Available residue chemistry data are insufficient to permit the Agency to conduct a tolerance reassessment. The Agency is unable to conclude that the current exemption from tolerance is justified. Accordingly the Agency is requiring data on plant and animal metabolism, storage stability, residue analytical methods, and residue levels in raw agricultural commodities and animals treated with rotenone. Data requirements are established based upon crop groupings, but registrants may instead propose to limit data development (and tolerances) to individual crops within the groupings.

Rationale: Data gaps exist for plant and animal metabolism and magnitude of residue for raw agricultural products, for processed food and feed items, and for foods which may bear residues as a result of treatments in food handling establishments.

4. Registrants must submit metabolism and residue data and propose tolerances for crops irrigated with water treated with rotenone. In addition, a label restriction prohibiting use of rotenone-treated water for irrigation purposes or its release for one-half mile above a potable water intake is specified. This restriction replaces that on current labels, which must be deleted, (treated water use is now restricted based upon survival of a sensitive test fish species for 24 hours).

Rationale: Treated water should not be used for domestic use or irritation until residues are reduced to an acceptable level. A bioassay using survival of a test fish for 24 hours is considered semiquantitative and non-specific. Available data indicate that rotenone degrades rapidly in water. Dilution with untreated water will further reduce residue concentrations in the one-half mile before use for potable water or irrigation purposes is permitted. This interim distance restriction should provide adequate reduction of residues until the Agency can establish necessary tolerances or an appropriate and practical time-based restriction on the use of rotenone-treated waters.

5. Registrants must amend labels which include directions for home garden uses so that the rates permitted for these uses are consistent with rates for commercial agricultural applications. If the rate for home garden application of any formulation to any site is greater than the maximum rate permitted for commercial application to that site, the registrant must submit appropriate residue data to support the home garden use.

Rationale: Use of pesticides in home gardens should not result in produce with residues exceeding those permitted in commercially treated commodities. Data must be submitted to show that proposed higher rates and or/increased number of applications will not result in any proposed tolerances being exceeded.

6. The Agency is not imposing a reentry interval for agricultural uses of rotenone. Protective clothing and equipment are not required.

Rationale: Rotenone does not meet the toxicity criteria of 40 CFR 158.390 for reentry data. Available toxicity data do not indicate a need for a reentry interval. or special protective clothing.

7. The Agency has identified certain data that will receive immediate review when submitted. The following studies have been identified to receive priority review:

171-4	Metabolism in Plants - Tolerance assessment
	Metabolism in Animals - Tolerance assessment
	Residue Analytical Methods - Tolerance assessment
	Magnitude of Residue in Irrigated Crops - Tolerance assessment
161-1	Hydrolysis - Tiered study
161-2	Photodegradation in water - Tiered study
162-4	Aerobic aquatic metabolism - Tiered study
165-3	Accumulation in Irrigated Crops

72-1	Fish toxicity using degradate - tiered
72-2	Invertebrate toxicity using degradate - tiered
72-3	Estuarine/marine toxicity using degradate - tiered

Rationale: Certain of the data being required by the Agency are essential to resolve risk concerns, or may trigger the need for further studies which should be initiated as soon as possible.

6. While the required data are under development all currently registered products containing rotenone as an active ingredient may be sold, distributed, formulated, and used, subject to the terms and conditions specified in the Standard. Registrants must agree to develop and provide additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency may choose not to cancel or withhold registration if the data are missing or inadequate (see FIFRA sec. 3(c)(2)(B) and 3(c)(7)). The issuance of this Standard provides the mechanism for obtaining necessary data. The data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain rotenone, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing use products (MPs) must contain rotenone. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1%.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing use products containing rotenone provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing use products may be labeled for formulation in to end use products only for the commodities listed below. The Use Index (EPA Compendium of Acceptable Uses)(for availability see page 1) lists all registered uses, as well as approved maximum application rates and frequencies.

Terrestrial and Greenhouse Food Uses
Terrestrial and Greenhouse Non-Food Uses
Aquatic Uses
Pet and Livestock Uses
Domestic, Commercial and Institutional Uses

D. REQUIRED LABELING

In order to remain in compliance with FIFRA, manufacturing use products must bear appropriate labeling as specified in 40 CFR 156.10. Appendix II contains information on label requirements.

No pesticide product containing rotenone may be released for shipment by the registrant after April 30, 1990, unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing rotenone may be distributed or sold after April 30, 1991, unless the product bears an amended label which complies with the requirements of this Standard.

The following specific information must appear on the labeling in order for products to remain in compliance with FIFRA:

1. Ingredients Statement

The ingredient statement for products must list the active ingredient as:

ACTIVE INGREDIENTS	
Rotenone	_______%
Other Associated Resins	_______%

In accordance with 40 CFR 162.10(g), the label of each pesticide product must contain the name and percentage by weight of not only the active ingredient, but also the percentage by weight of all inert ingredients.

2. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in Use Patterns, Chapter II, Section C. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in TABLE A for that use pattern.

3. Precautionary Statements

Statements for Manufacturing-Use Products

This Pesticide is extremely toxic to fish. Do not discharge into lakes, streams, ponds, estuaries, oceans, or other public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Statements for End Use Products (Terrestrial, Food and Non-food and Domestic Outdoor

This pesticide is extremely toxic to fish. Do not apply directly to water or wetlands (swamps, bogs, marshes, potholes). Runoff and drift from treated areas may be hazardous to aquatic organisms in adjacent sites. Do not contaminate water when disposing of equipment washwaters.

Statement for End Use Products (For Cats and Dogs)

Do not use on puppies or kittens less than 4 weeks old.

Statements for End Use Products (Agricultural Uses).

Do not feed treated foliage to livestock.

Do not apply rotenone in such a manner as to directly or through drift expose workers or other persons. The area being treated must be vacated by unprotected persons. Do not enter treated areas without protective clothing until sprays have dried or dust has settled.

Statements for End use Products (Cranberry Use)

RESTRICTED USE PESTICIDE
Due to Aquatic Toxicity

This pesticide is extremely toxic to fish. Runoff and drift from treated areas may be hazardous to aquatic organisms in adjacent sites. Do not contaminate untreated water when disposing of equipment washwaters. Do not use water treated with rotenone to irrigate crops (other than cranberry) or release within 1/2 mile upstream of a potable water or irrigation water intake in a standing body of water such as a lake, pond, or reservoir.

Statements for End Use Products (Piscicide Use)

RESTRICTED USE PESTICIDE
Due to Aquatic Toxicity

This pesticide is extremely toxic to fish. Fish kills are expected at recommended rates. Consult your State Fish and Game Agency before applying this product to public waters to determine if a permit is needed for such an application. Do not contaminate untreated water when disposing of equipment washwaters.

Do not use dead fish as food or feed.

Do not use water treated with rotenone to irrigate crops or release within 1/2 mile upstream of a potable water or irrigation water intake in a standing body of water such as a lake, pond or reservoir.

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by an end use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the generic data exemption[3], the data requirements listed in Table C.

3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to the data requirements in Table A.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will

submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Office of Pesticide Programs
OPP Mailroom (H-7508C)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Attn: Rotenone Registration Standard

All submittals in response to this Registration Standard are non-fee items, including 90-day responses, protocols and waiver requests, data, and revised labeling. Submittals must be clearly identified as being in response to the Registration Standard. Under no circumstances may Registration Standard responses be combined with other types of filings for which fees are required.

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 9 months of receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately

notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

TGUIDE-1

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE TECHNICAL GRADE OF THE ACTIVE INGREDIENT.

Data Requirement	Composition[1]	Does EPA have data to satisfy this requirement?[2]	Bibliographic Citation[2]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
158 Subpart C-Product Chemistry Product Identity and Composition					
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No	N/A	Yes[3]	6 months
61-3 - Discussion of Formation of Impurities	TGAI	No	N/A	Yes[4]	6 months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	TGAI	No	N/A	Yes[5]	12 months
Physical and Chemical Characteristics					
63-2 - Color	TGAI	No	N/A	Yes[6]	6 months
63-3 - Physical State	TGAI	No	N/A	Yes[6]	6 months
63-4 - Odor	TGAI	No	N/A	Yes[6]	6 months
63-5 - Melting Point	TGAI	No	N/A	Yes[6,7]	6 months
63-6 - Boiling Point	TGAI	No	N/A	Yes[6,8]	6 months
63-7 - Density, Bulk Density or Specific Gravity	TGAI	No	N/A	Yes[6]	6 months
63-8 - Solubility	TGAI or PAI	No	N/A	Yes[6]	6 months
63-9 - Vapor Pressure	TGAI or PAI	No	N/A	Yes[6]	6 months
63-10 - Dissociation Constant	TGAI or PAI	No	N/A	Yes[6]	6 months
63-11 - Octanol/Water Partitioning Coefficient	PAI	No	N/A	Yes[6,9]	6 months
63-12 - pH	TGAI	No	N/A	Yes[6,10]	6 months
63-13 - Stability	TGAI	No	N/A	Yes[6]	6 months
Other Requirements:					
64-1 - Submittal of Samples	N/A	N/A	N/A	No	

(Continued, footnotes follow.)

TABLE A. (Continued).

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[1] TGAI = technical grade of the active ingredient. PAI = purified active ingredient.

[2] Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

[3] Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

[4] A detailed discussion of all impurities that are or may be present at $\geq$0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

[5] Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation data (accuracy and precision) must be submitted for each analytical method used.

[6] Physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, partition coefficient, pH, and stability) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

[7] Data needed if the technical chemical is a solid at room temperature.

[8] Data required if the technical product is a liquid at room temperature.

[9] Data required if the technical product is organic and nonpolar.

[10] Data required if the test substance is dispersible in water.

TABLE A. GENERIC DATA REQUIREMENTS FOR ROTENONE

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission[1]
158.240 Residue Chemistry					
171-2. Chemical Identity[2]					
171-3. Directions for use				Yes[2]	3 months
171-4. Nature of the residue (Metabolism) - Plants	PAIRA	No	N/A.	Yes[3]	18 months
171-4. Nature of the residue (Metabolism) - Livestock	PAIRA and plant metabolites	No	N/A.	Yes[4,5,6]	18 months
171-4. Residue analytical methods	TGAI and metabolites	Partially	00072106. 00157851. 05005830.	Yes[7,8]	18 months
171-4. Storage stability	TEP and metabolites	Partially		Yes[9]	18 months
171-4. Magnitude of the residue in plants					
Root and Tuber Veg.	TEP	No		Yes[10]	18 months
-Processed Potatoes	TEP	No		Yes[11]	24 months
Bulb Vegetables	TEP	No		Yes[12]	18 months

(Continued, footnotes follow.)

TABLE A. (Continued).

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
Leafy Vegetables	TEP	No		Yes[13]	18 months
Brassica Leafy Vegetables	TEP	No		Yes[14]	18 months
Legume Vegetables	TEP	No		Yes[15,16]	18 months
Fruiting Vegetables	TEP	No		Yes[17]	18 months
-Processed tomato products				Yes[18]	24 months
Cucurbit Vegetables	TEP	No		Yes[19]	
Citrus Fruits	TEP	No		Yes[20]	18 months
-Processed citrus products				Yes[21]	24 months
Pome Fruits	TEP	No		Yes[22]	18 months
-Processed apple products				Yes[23]	24 months
Stone Fruits	TEP	No		Yes[24]	18 months
-Prunes				Yes[25]	24 months
Small Fruits and Berries	TEP	No		Yes[26]	18 months
-Raisons(processed grapes)				Yes[27]	24 months
Tree Nuts	TEP	No		Yes[28]	6 months
Cereal Grains	TEP	No		Yes[29]	18 months
-Processed grains				Yes[30]	24 months

(Continued, footnotes follow.)

TABLE A. (Continued).

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
Non-grass Animal Feeds	TEP	No		Yes[31]	18 months
Miscellaneous Commodities					
- Artichokes	TEP	No		Yes[32]	18 months
- Asparagus	TEP	No		Yes[33]	18 months
- Cottonseed	TEP	No		Yes[34]	18 months
-Cottonseed byproducts				Yes[35]	24 months
- Mint	TEP	No		Yes[36]	18 months
-Mint oil & hay				Yes[37]	24 months
- Okra	TEP	No		Yes[38]	18 months
- Persimmons	TEP	No		Yes[39]	18 months
- Pomegranates	TEP	No		Yes[40]	18 months
- Sugarcane	TEP	No		Yes[41]	18 months
-Sugarcane Byproducts	TEP	No		Yes[42]	24 months
Tobacco	TEP and PAIRA			Yes[43,44]	
171-4. Magnitude of residue in Meat/Milk/Poultry/Eggs	TGAI or Plant Metabolites	Partially	00045126. 05005830.	Reserved[45]	18 months
171-4. Food Handling Establishments	TEP and PAIRA	No		Yes[46,47]	24 months

(Continued, footnotes follow.)

TABLE A. (Continued).

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
171-4. Magnitude of residue in Potable water, fish, and irrigated crops					
-Fish & shellfish	TEP and PAIRA	Partially	00157851	Yes[48]	15 months
-Irrigated crops	TEP and PAIRA	Partially		Yes[49]	15 months

1. The same chemical identity data are required as under 158.120, with emphasis on impurities that could constitute residue problems. Refer to Product Chemistry Data Requirements tables.

2. The registrants must amend those labels which include directions for homeowner uses so that the rates permitted for these uses are expressed in a manner consistent with rates listed for commercial applications. If the rate for homeowner application of any formulation to any site is greater than the maximum rate permitted for commercial application to that site, the registrant must submit appropriate residue data to support the homeowner use. Submit doesage recalculations within three months and indicate at that time whether labels will be revised or a committment made to generate residue data.

3. Data depicting the distribution and metabolism of ring-labeled [^{14}C]rotenone in or on three dissimilar food crops (e.g., a root crop, oilseed crop, and a leafy vegetable). If metabolism is not similar in the three crops additional studies using other crops may be required. A completely characterized test substance (including impurities) representative of technical rotenone used in commercial formulations must be applied foliarly several times up to and including the day of harvest at rates sufficiently high to permit characterization of ^{14}C-residues. The identities and quantities of residues in or on mature plant parts must be determined in order to elucidate terminal residues. Representative samples must also be analyzed by proposed enforcement methods including Multiresidue Protocols I-IV to ascertain that all residues of concern are determined.

TABLE A. (Continued).

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4. Metabolism studies utilizing ruminants and poultry. Animals must be dosed orally for a minimum of 3 days with ring-labeled [^{14}C]rotenone (the test substance must be completely characterized, including impurities, and representative of technical rotenone used in commercial formulations) at a level sufficient to make residue identification and quantification in tissues and milk possible. Milk and eggs must be collected twice daily during the dosing period. Animals must be sacrificed within 24 hours of administration of the final dose. The distribution and identity of residues must be determined in eggs, milk, liver, kidney, muscle, and fat. Samples from these studies must also be analyzed using all proposed enforcement methods (including all FDA Multiresidue protocols [I-IV]) to ascertain that the methods are capable of adequately recovering all residue of concern.

5. Metabolism studies using cattle and poultry reflecting direct animal treatment. These data are needed because rotenone is registered for use as a premise treatment in farm animal loafing areas and as a direct treatment to birds, dairy animals, goats and horses. Animals must be sprayed at a rate sufficiently high to permit complete characterization of ^{14}C-residues and sacrificed within one day of the final application. ^{14}C-Residues must be quantified and characterized in muscle, fat, liver, kidney, milk, and eggs. Eggs and milk must be collected twice daily throughout the treatment period. Samples from these studies must also be analyzed using all proposed enforcement methods (including all FDA Multiresidue protocols [I-IV]) to ascertain that the methods are capable of adequately recovering all residues of concern.

6. Data depicting the nature of rotenone residues in swine are also required unless the metabolism of rotenone in ruminants or poultry does not differ significantly from that in rats.

7. A complete description of all methods used for collection of residue data submitted in response to this Standard must be submitted along with method validation data (sensitivity, accuracy, and precision).

8. Additional residue and validation data and appropriate methods may be required if requested metabolism/degradation studies reveal additional metabolites of concern.

9. All residue data required in this Standard must be accompanied by information specifying the storage interval and conditions for samples analyzed. Data must also be submitted depicting the storage stability of the residues of concern under the same conditions and intervals specified. In laboratory tests using fortified samples, the pure active ingredient and pure metabolites (if necessary) must be used. However, if field weathered samples are used, the test substance must be a typical end-use product.

TABLE A. (Continued).

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10. Data depicting rotenone residues of concern in or on the following crops harvested 1 day after the last of multiple foliar treatments according to the following regimes: (i) beets treated at 0.6 lb ai/A and carrots and radishes treated at 0.5 lb ai/A with a WP/D formulation (applied as a dust and as a spray in separate tests) at 7- to 10-day intervals; (ii) potatoes treated at 0.75 lb ai/A with a WP/D and an EC at 5- to 10-day intervals; (iii) potatoes treated aerially (in FL only) with a 0.5% SC/L at 2 pt prod/A in 1-3 gal/A at 5- to 7-day intervals to support the FL 24(c) label (FL780061); and (iv) turnips treated with the 0.5% EC at 1 pt prod/A in 1 qt vegetable oil at 7- to 10-day intervals using aerial ULV equipment. Tests must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce). A tolerance for residues in or on members of the Root and Tuber Vegetables Group must be proposed based on the required data. Alternatively, the registrant(s) must submit a protocol delineating the products, crop sites, and label directions they wish to retain.

11. Data depicting rotenone residues of concern in granules, chips, wet peel, and dry peel processed from potatoes bearing measurable weathered residues. If residues concentrate, appropriate food/feed additive tolerances must be proposed.

12. Data depicting rotenone residues of concern in or on green onions and garlic harvested 1 day following the last of multiple foliar applications made at 7- to 10-day intervals with the 5% D at 0.5 lb ai/A and the 5% WP at 0.5 lb ai/100 gal, in separate tests. Tests must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce). A tolerance for residues in or on members of the Bulb Vegetables Group (excluding bulb onions) must be proposed based on the required data. Alternatively, the registrant(s) must submit a protocol delineating the products, crop sites, and label directions they wish to retain.

13. Data depicting rotenone residues of concern in or on the following crops harvested 1 day after the last of multiple foliar applications: (i) lettuce head and leaf varieties) and spinach treated at 5- to 7-day intervals with a WP/D formulation (applied dry and as a spray in separate tests) at 0.5 lb ai/A; (ii) lettuce treated with the 0.5% EC formulation at 0.5 lb ai/A at 5- to 7-day intervals; (iii) celery treated with a WP at 1 lb ai/100 gal at 24-hr intervals; (iv) celery treated with the 0.5% SC/L at 2 pt prod/A in 1-3 gal water at 5- to 7-day intervals support the FL 24(c) label (FL780061); and (v) celery treated with the 0.5% EC at 24-hr intervals at 2 pt prod/25-100 gal (ground) and at 1 pt prod/A in 1 qt vegetable oil using aerial ground equipment.
Tests must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce). A tolerance for residues in or on members of the Leafy Vegetables Group must be proposed based on the required data. Alternatively, the registrant must submit a protocol delineating the products, crop sites, and label directions they wish to retain.

TABLE A. (Continued).

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14. Data depicting rotenone residues of concern in or on broccoli, cabbage, and mustard greens harvested 1 day after the last of multiple foliar applications with a WP/D formulation (applied dry and as a spray in separate tests) at 0.5 lb ai/A; (ii) the 0.5 lb/gal EC formulation applied at 0.5 lb ai/A; (iii) the 0.5% EC formulation at 1 pt formulation/A using aerial ULV equipment; and (iv) the 0.5% SC/L formulation at 2 pt formulation in 1-3 gal/A to support the FL 24(c) label (FL780061). Tests must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce). A tolerance for residues in or on members of the Brassica Leafy Vegetables Group must be proposed based on the required data. Alternatively, the registrant(s) must submit a protocol delineating the products, crop sites, and label directions they wish to retain.

15. Data depicting rotenone residues of concern in or on beans and peas (one succulent and one dry variety of each, in separate tests) harvested 1 day following the last of multiple foliar applications made at 5- to 7-day intervals with (i) a WP/D formulation (as a dust and a spray, in separate tests) at 1 lb ai/A for beans and 0.75 lb ai/A for peas; (ii) the 0.5% EC formulation at 2 pt prod/A in 25-100 gal and at 1 pt formulation/A in 1 qt vegetable oil using aerial ULV equipment; and (iii) the 0.5% SC/L formulation at 2 pt formulation in 1 gal/A to support the FL 24(c) label (FL780061). Tests must be conducted in states that represent the major growing regions for beans according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce). Tolerances for residues in or on beans (succulent and dry) and peas must be proposed based on the required data or a crop group tolerance (excluding soybeans) may be proposed. Alternatively, the registrant must submit a protocol delineating the products, crop sites, and label directions they wish to retain.

16. Since bean and pea vines and hay are raw agricultural commodities, the registrant(s) must propose tolerances for residues of rotenone in or on bean and peas vines and hay and submit appropriate supporting residue

17. Data depicting rotenone residues of concern in or on eggplant and tomatoes harvested 1 day following multiple foliar applications (at 5to 7-day intervals for eggplant and 7- to 10-day intervals for tomatoes) with (i) a WP/D formulation, applied dry and as a spray in separate tests, at 1 lb ai/A; (ii) an EC formulation applied at 1 lb ai/A; (iii) the 0.5% EC formulation at 1 pt formulation/A in 1 qt vegetable oil using aerial ULV equipment. Also, peppers and tomatoes are to be treated repeatedly at 5- to 7-day intervals with the 0.5% SC/L formulation at 2 pt formulation in 1-3 gal/A to support the FL 24(c) label (FL780061). Tests must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce). A tolerance for residues in or on members of the Fruiting Vegetables Group must be proposed based on the required data. Alternatively, the registrant(s) must submit a protocol delineating the products, crop sites, and label directions they wish to retain.

18. Data depicting rotenone residues of concern in products (dry pomace, puree, catsup, and juice) processed from tomatoes bearing measurable, weathered residues. If residues concentrate in any product, appropriate food/feed additive tolerances must be proposed.

TABLE A. (Continued).

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19. Data depicting rotenone residues of concern in or on cucumbers, melons (cantaloupe or muskmelon), and summer squash (in separate tests) harvested 1 day following multiple foliar applications with (i) a WP/D formulation, applied dry and as a spray in separate tests, at 0.5 lb ai/A; (ii) the 0.5% EC formulation at 2 pt prod/A in 25-100 gal water and at 1 pt formulation/A in 1 qt vegetable oil using aerial ULV equipment; (iii) and the SC/L formulation at 2 pt formulation in 1 gal/A to support the FL 24(c) label (FL780061). Tests must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce). A tolerance for residues in or on members of the Cucurbit Vegetables Group must be proposed based on the required data. Alternatively, the registrant(s) must submit a protocol delineating the products, crop sites, and label directions they wish to retain.

20. Data depicting rotenone residues of concern in or on representative group members sweet orange, lemon, and grapefruit harvested 1 day following the last of multiple foliar applications of the 0.5% EC at 2 pt prod/100 gal, 0.5% SC/L at 2 pt prod/A in 1-3 gal, and the 5% WP 0.75 lb ai/A or 2 lb ai/100 gal, whichever is the greatest per acre rate. Tests must be conducted in FL to represent the SLN use (FL780061) of the 0.5% SC/L formulation and in states which represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce) for use of other formulations. A tolerance for residues in or on members of the Citrus Fruits Group must be proposed based on the required data. Alternatively, the registrant(s) must submit a protocol delineating the products, crop sites, and label directions they wish to retain.

21. Data depicting rotenone residues of concern in wet and dried pulp, oil, molasses, and juice processed from citrus bearing measurable weathered residues. If residues concentrate, appropriate food/feed additive tolerances must be proposed.

22. Data depicting rotenone residues of concern after multiple foliar applications to the following crops: (i) apples and pears treated with the 0.5% SC/L at 2 pt prod/A in 1-3 gal spray; (ii) apples and pears treated with the 0.5% EC at 2 pt prod/A in 100 gal and at 1 pt prod/A in 1 qt vegetable oil using aerial ULV equipment; (iii) pears treated with a WP at 1 lb ai/100 gal and a D at 0.5 lb ai/A; and (iv) apples treated with a WP/D at 0.5 lb ai/A and 1 lb ai/100 gal (applied as a dust and as a spray, in separate tests). Fruit must be harvested 1 day following the last of multiple foliar applications. Tests must be conducted in FL to represent the SLN use (FL780061) of the SC/L formulation and in states which represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce) for use of other formulations. A tolerance for residues in or on members of the Pome Fruits Group must be proposed based on the required data. Alternatively, the registrant(s) must submit a protocol delineating the products, crop sites, and label directions they wish to retain.

TABLE A. (Continued).

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23. Data depicting rotenone residues of concern in juice and wet and dry pomace processed from apples bearing measurable weathered residues. If residues concentrate in juice and dry pomace, appropriate food/feed additive tolerances must be proposed.

24. Data depicting rotenone residues of concern in or on the following representative commodities harvested 1 day after the last of multiple foliar applications: (i) cherries treated with a WP/D formulation at 1 lb ai/A (as a dust and spray in separate tests); (ii) peaches treated with the 0.5% EC formulation at 2 pt prod/A in 25-100 gal and at 1 pt prod/A in 1 qt vegetable oil by aerial ULV equipment; (iii) peaches and plums treated with a D at 0.5 lb ai/A and the 5% WP at 1 lb ai/100 gal; and (iv) peaches treated with the 0.5% SC/L at 2 pt prod/A in 1-3 gal water at 5- to 7-day intervals. Tests representative of the SLN use (FL780061) must also be conducted in FL using the SC/L formulation applied to peaches using aerial and ground equipment, in separate tests. Tests must be conducted in states which represent the major growing regions for each crop according to the latest edition of *Agricultural Statistics* (USDA) or the *1982 Census of Agriculture* (U.S. Dept. of Commerce) for use of other formulations. A tolerance for residues in or on members of the Stone Fruits Group must be proposed based on the required data. Alternatively, the registrant(s) must submit a protocol delineating the products, crop sites, and label directions they wish to retain.

25. Data depicting rotenone residues of concern in dried prunes processed from plums bearing measurable weathered residues. If residues concentrate in dried prunes, an appropriate food additive tolerance must be proposed.

26. Data depicting rotenone residues of concern in or on representative group members blackberry/*Rubus*, blueberry, grape, and strawberry harvested 1 day following the last of multiple foliar applications according to the following treatment regimes: (i) blackberries receiving two treatments at 2- to 3-week intervals of a WP/D (as a dust and spray in separate tests) at 0.75 lb ai/A; (ii) blueberries receiving three treatments at 10-day intervals of the 1% D at 2 lb ai/A and the 5% WP at 0.75 lb ai/100 gal; (iii) grapes receiving multiple treatments with a WP/D (as a dust and spray in separate tests) at 0.5 lb ai/A at 10- to 14- day intervals; and (iv) strawberries receiving multiple treatments at 7- to 10-day intervals, of a WP/D (as a dust and spray in separate tests) at 0.5 lb ai/A and the 0.5% EC at 2 pt prod/100 gal. A tolerance for residues in or on members of the Small Fruits and Berries Group (except cranberries) must be proposed based on the required data. Alternatively, the registrant(s) must submit a protocol delineating the products, crop sites, and label directions they wish to retain.

27. Data depicting rotenone residues of concern in raisins, raisin waste, juice, and pomace (wet and dry) processed from grapes bearing measurable weathered residues. If residues concentrate in any processed product, appropriate food/feed additive tolerances must be proposed.

28. The registrants must amend those labels which include directions for homeowner and/or commercial uses on almonds and walnuts so that the rates permitted for these uses are expressed in a manner consistent with rates listed for commercial applications to other orchard trees. Residue data must be submitted that reflect the amanded labels. Tolerances must the proposed based on the submitted data. Tests must be conducted in geographically representative areas according to Agricultural Statistics (USDA) or the Census of Agriculture (Dept. of Commerce). Submit doesage recalculations within three months and indicate at that time whether labels will be revised or a commitment made to generate residue data.

29. Data depicting rotenone residues of concern in or on field, pop, and sweet corn harvested 1 day following the last of four foliar applications of the 1% WP/D (including separate tests for dry and spray applications) at 3.5 lb ai/A at 2- to 10-day intervals. Residue data are required for grain sorghum harvested 1 day following the last of multiple foliar applications at 5- to 7-day intervals of the 0.5% SC/L formulation using aerial and ground equipment at 2 pt prod/A in 1-3 gal water conducted in FL to represent the SLN use (FL780061). Tests must be conducted in states which represent the major growing regions for corn according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce) for the EC formulation tests. Tolerances for residues in or on corn and grain sorghum must be proposed based on the required data. Alternatively, the registrant(s) must submit a protocol delineating the products, crop sites, and label directions they wish to retain.

30. Data depicting rotenone residues of concern in flour, starch, and grain dust of grain sorghum and in crude and refined oils, wet and dry milling products (including starch, crude and refined oils, grits, meal, and flour), and grain dust processed from field corn grain bearing measurable weathered residues. If residues concentrate, appropriate food/feed additive tolerances must be proposed.

31. Data depicting rotenone residues of concern in or on the representative group members alfalfa and clover harvested at regular intervals following the last of multiple foliar applications of the EC and SC/L formulations made at 5- to 7-day inntervals , in separate tests, at 2 pt prod/A. Tests must be conducted in FL to represent the SLN use of the SC/L formulation and, for the EC, in states which represent the major growing regions for alfalfa and clover according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce) for the EC formulation. A tolerance for residues in or on members of the Non-grass Animal Feeds Group must be proposed based on the required data. Alternatively, the registrant(s) must submit a protocol delineating the products, crop sites, and label directions they wish to retain.

32. Data depicting rotenone residues of concern in or on artichokes harvested 1 day following the last of multiple foliar applications of the EC formulation at 2 pt prod/A. Ground equipment (25-100 gal spray/A) and aerial ULV equipment (1 qt vegetable oil/A) must be used. Tests must be conducted in CA which produces virtually all U.S.-grown artichokes according to the 1982 Census of Agriculture. A tolerance for residues in or on artichokes must be proposed based on the required data.

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33. Data depicting rotenone residues of concern in or on asparagus harvested 1 day following the last of multiple foliar applications, at 7- to 10-day intervals, of a WP/D (including separate tests with dry and spray) formulation at 0.5 lb ai/A and 0.5 lb ai/100 gal. Tests must be conducted in CA (36%), WA (31%), and MI (20%), which represent the major asparagus growing regions according to the 1982 Census of Agriculture (U.S. Dept. of Commerce) parenthetic numbers are percent of U.S. acreage. A tolerance for residues in or on asparagus must be proposed based on the required data.

34. Data depicting rotenone residues of concern in or on seed and forage of cotton harvested at regular intervals following the last of multiple foliar applications of the 0.5% EC formulation at: (i) 2 pt prod/A in 25-100 gal water per acre using aerial and ground equipment and (ii) 1 pt prod/A in 1 qt vegetable oil per acre using ULV equipment. Tests must be conducted in CA (25%), TX (31%), and MS (12%) which represent the major cotton growing regions according to the 1986 Agricultural Statistics (USDA). Tolerances for residues in or on cotton must be proposed based on the required data.

35. Data depicting rotenone residues of concern in meal, hulls, soapstock, and crude and refined oils processed from cottonseed bearing measurable weathered residues. If residues concentrate, appropriate food/feed additive tolerances must be proposed.

36. Data depicting rotenone residues of concern in or on mint hay harvested 1 day following the last of multiple foliar applications of the D formulation at 0.25 lb ai/A made at 5- to 7-day intervals. Tests must be conducted in OR or WA which represent 91% of the mint growing area according to the 1986 Agricultural Statistics (USDA). A tolerance for residues in or on spent mint must be proposed based on the required data.

37. Data depicting rotenone residues of concern in oil and spent hay processed from mint hay bearing measurable weathered residues. If residues concentrate, appropriate food/feed additive tolerances must be proposed.

38. Data depicting rotenone residues of concern in or on okra harvested 1 day following the last of multiple foliar applications, made at 7- to 10-day intervals, of the 1.5% WP/D formulation at 0.75 lb ai/A (as both a dust and a spray in separate tests). Tests must be conducted in GA and TX which represent 66% of the okra growing area according to the 1982 Census of Agriculture (U.S. Dept. of Commerce). A tolerance for residues in or on okra must be proposed based on the required data.

39. Data depicting rotenone residues of concern in or on persimmon harvested 1 day following the last of multiple foliar applications of the WP formulation made at 10- to 14-day intervals at 1 lb ai/100 gal. Tests must be conducted in CA which produces 96% of the persimmon crop according to the 1982 Census of Agriculture (U.S. Dept. of Commerce). A tolerance for residues in or on persimmons must be proposed based on the required data.

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40. Pomegranates grown in CA are to be harvested 1 day after the last of multiple foliar applications of the 5% WP at 1 lb ai/100 gal at 14-day intervals. Fruit are to be analyzed for rotenone residues of concern. [CA produces virtually 100% of the U.S. pomegranate crop according to the *1982 Census of Agriculture* (U.S. Dept. of Commerce).] A tolerance for residues in or on pomegranates must be proposed based on the required data.

41. Data depicting rotenone residues of concern in or on cane and forage of sugarcane harvested at regular intervals following the last of multiple foliar applications (at 5- to 7-day intervals) of the 0.5% SC/L formulation at 2 pt prod/A using ground and aerial equipment in separate tests. Tests must be conducted in FL to reflect the registered SLN use. A tolerance for residues in or on cane and forage of sugarcane must be proposed based on the required data.

42. Data depicting rotenone residues of concern in molasses, refined sugar, and bagasse processed from sugarcane bearing measurable weathered residues. If residues concentrate, appropriate food/feed additive tolerances must be proposed.

43. Data depicting rotenone residues of concern in or on green and cured or dry tobacco harvested at regular intervals following the last of multiple foliar and plant bed applications of the D and WP/D formulations, in the same tests, at 0.08 oz ai/100 sq yd (plant bed) and 0.5 lb ai/A (field), respectively. Tests are to be conducted in KY and NC which represent >75% of all U.S. tobacco production according to the 1986 *Agricultural Statistics* (p. 93).

44. If rotenone residues of concern are ≥0.1 ppm in or on dry or cured tobacco, pyrolysis products derived from the active ingredient must be characterized and the level of the residue in smoke must be quantified. (Ring-labeled [^{14}C]rotenone must be used for identification of pyrolysis products.)

45. Presently, the nature of the residue in animals is not adequately understood. In addition, numerous data gaps exist concerning the magnitude of the residue in feed items of animals. Upon receipt of data requested in the section "Nature of the Residue in Animals" and that requested for feed commodities, the need for and nature of tolerances for residues in animal products will be determined. The specific data requirements regarding the magnitude of the residues in animal products, possibly including direct animal treatments, will be determined when all requested data regarding metabolism in animals and magnitude of the residue in feed items have been received.

46. Data depicting the nature of the residue in representative food products from grain mills, food processing plants, restaurants, and fruit packing plants resulting from known contamination of ring-labeled [^{14}C]rotenone. Tests must represent the normal range of heating and processing procedures following fortification with [^{14}C]rotenone at typical stages where contamination resulting from treatment of the premise might occur. Characterization of residues must be conducted in samples representing the range of normal shelf life for food.

TABLE A. (Continued).

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products.

47. Data depicting the magnitude of rotenone residues of concern in food products resulting from applications of rotenone in grain mills, food processing plants, restaurants, and fruit packing plants. Tests are required in these establishments utilizing EC, RTU, and PrL formulations in indoor space spray treatments. Tests must represent worst case scenarios for potential residue contamination of food products which might include, but not be limited to, some of the following: (i) particulate aerosol contact with packaged products or unwrapped fresh produce present and/or on display at the time of rotenone treatment; (ii) contact of packaged foods with treated surfaces, such as flour sacks stacked on treated floor surfaces in storage areas; (iii) accidental treatment of food work surfaces and subsequent contact of food before surfaces are cleaned; (iv) treatment occurring near stacks of new or cleaned product containers that are then filled without being cleaned; or (v) tracking of residue by insects or rodents from treated areas to food or food contact surfaces.

48. A metabolism study must be submitted in which fish and shellfish are exposed (for at least 3 days) to water containing [^{14}C]rotenone at 0.25 ppm or a concentration sufficiently high to permit complete quantification and characterization of ^{14}C-residues in edible tissues (flesh and skin). Representative samples must also be analyzed by proposed enforcement methods including Multiresidue Protocols I-IV to ascertain that all residues of concern are determined.

49. The registrant(s) must provide residue data and propose tolerances for residues in or on all crops resulting from use of treated irrigation water. Pending acceptance of proposed tolerances and appropriate label restrictions, labels of products containing rotenone must include a statement precluding use of treated water for irrigation.

TABLE A
GENERIC DATA REQUIREMENTS FOR ROTENONE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.290 - Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	PAIRA	A,B,D, E,F,H	No	---	Yes	9 Months
Photodegradation						
161-2 - In water	PAIRA	A,B,D	No	---	Yes	9 Months
161-3 - On soil	TGAI or PAIRA	A,B	No	---	Yes	9 Months
161-4 - In Air	TGAI or PAIRA	A,B	No	---	Reserved[1]	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	PAIRA	A,B,E, F,H	No	---	Yes	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A,B	No	---	NO[2]	
162-3 - Anaerobic Aquatic	TGAI or PAIRA	D	Yes	00141273	No	
162-4 - Aerobic Aquatic	TGAI or PAIRA	D	No	---	Yes	27 Months
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	PAIRA	A,B,D, E,F,H	Partial	00157850	Yes[3]	12 Months
163-2 - Volatility (Lab)	TEP	A,B,E, F	No	---	Reserved[1]	
163-3 - Volatility (Field)	TEP	A,B,E, F	No	---	Reserved[1]	

TABLE A
GENERIC DATA REQUIREMENTS FOR ROTENONE

Data Requirement	Test Substance[1]	Use Patterns[2]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?[3]	Time Frame for Submission
§158.290 - Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B,H	No	---	Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	D	No	---	Yes	27 Months
164-3 - Forestry	TEP	---	No	---	No[4]	
164-4 - Combination and Tank Mixes	TEP	---	No	---	No[5]	
164-5 - Soil, Long-term	TEP	A,B,H	No	---	Reserved[6]	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No	---	Yes	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No	---	Reserved[7]	
165-3 - Irrigated Crops	TEP	D	No	---	Yes	39 Months
165-4 - In Fish	TGAI or PAIRA	A,B	Yes	00146183	No	
165-5 - In Aquatic Non-Target Organisms	TEP	D	No	---	No[8]	

TABLE A
GENERIC DATA REQUIREMENTS FOR ROTENONE

§158.290 - Environmental Fate - Continued

1/ This study may be required, depending on rotenone's vapor pressure.

2/ This study is not required because an acceptable anaerobic aquatic study has been submitted.

3/ Additional data are required on the mobility of rotenone and its metabolites in soil and sediment.

4/ There are no forestry uses.

5/ This data requirement is not being imposed at this time.

6/ These data may be required, depending on the results of the field dissipation studies.

7/ These data may be required, depending on the results of the confined rotational crop study.

8/ This data requirement is not being imposed at this time because of rotenone's low bioaccumulation potential in edible tissues, and rapid degradation in water.

TABLE A
GENERIC DATA REQUIREMENTS FOR ROTENONE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Time Frame for Submission
§158.340 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral - Rat	TGAI	ALL	YES	00145496	NO	
81-2 - Acute Dermal -	TGAI	ALL	NO		YES	9 MONTHS
81-3 - Acute Inhalation - Rat	TGAI	ALL	NO		YES	9 MONTHS
81-4 - Eye Irritaion - Rabbit	TGAI	ALL	NO		YES	9 MONTHS
81-5 - Dermal Irritation - Rabbit	TGAI	ALL	NO		YES	9 MONTHS
81-6 - Dermal Sensitization - Guinea Pig	TGAI	ALL	NO		YES	9 MONTHS
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	ALL	NO		NO	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding -						
Rodent	TGAI	ALL	YES	00156739, 00141408	NO[1]	
Non-rodent	TGAI	ALL	YES	00141406	NO[2]	

TABLE A
GENERIC DATA REQUIREMENTS FOR ROTENONE

ata Requirement	Test Substance 1/	Use Patterns 2/	Does EPA Have Data?	Bibliographic Citation	Must Additional 3/ Data be Submitted	Time Frame for Submission
158.340 Toxicology (Cont.)						
82-2 - 21-Day Dermal-	TGAI	ALL	NO		YES	12 MONTHS
82-3 - 90-Day Dermal-	TGAI	ALL	NO		NO[3]	
82-4 - 90-Day Inhalation -	TGAI	ALL	NO		NO[4]	
82-5 - 90-Day Neurotoxicity-	TGAI	ALL	NO		NO[5]	
CHRONIC TESTING:						
83-1 - Chronic Toxicity -						
Rodent	TGAI	ALL	PARTIALLY[6]	00156739	YES	50 MONTHS
Non-rodent	TGAI	ALL	YES	00141406	NO	
83-2 - Oncogenicity Study -						
Rat	TGAI	ALL	PARTIALLY	00156739, 40179801	NO	
Mouse	TGAI	ALL	PARTIALLY	40179801	NO	
83-3 - Teratogenicity -						
Rat	TGAI	ALL	YES	00144294	NO	
Rabbit	TGAI	ALL	YES	00103047, 00141407	NO	
83-4 - Reproduction -	TGAI	ALL	YES	00141408	NO	

TABLE A
GENERIC DATA REQUIREMENTS FOR ROTENONE

Data Requirement	Test Substance 1/	Use Patterns 2/	Does EPA Have Data?	Bibliographic Citation	Must Additional 3/ Data be Submitted	Time Frame for Submission
§158.340 Toxicology (continued)						
MUTAGENICITY TESTING						
84-2 - Gene Mutation	TGAI	ALL	YES	40170502, 40170506 40170505, 00144292 00093702	NO	
84-2 - Chromosomal Aberration	TGAI	ALL	YES	00093702, 40179801	YES[7]	12 months
84-2 - Other Mechanisms of Mutagenicity	TGAI	ALL	YES	00144292	NO	
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA	ALL	YES	00145496	NO	
85-2 - Domestic Animal Safety	Choice	ALL	NO	--------	NO	

TABLE A
GENERIC DATA REQUIREMENTS FOR ROTENONE

1. This requirement is waived based on the requirement of a chronic toxicity study in the rat.

2. This study is not required based on the submission of an acceptable 6-month feeding study in the dog.

3. This study is not required because existing end-uses are not expected to result in repeated human skin contact.

4. This study is not required because existing end-uses are not expected to result in repeated inhalation exposure.

5. This study is not required because there is no positive acute neurotoxicity study, and rotenone has shown no evidence that it causes neurotoxicity in mammalian species.

6. This study can be upgraded and accepted when histopathology for the low and mid dose groups becomes available.

7. Final reports for Sister Chromatid Exchange and Chromosomal Aberration assays summarized by NTP (40179801) are needed to support a complete assessment of the mutagenicity studies. An in vivo cytogenetics study is required.

TABLE A
GENERIC DATA REQUIREMENTS FOR ROTENONE

Data Requirement	Test Substance[1]	Use Pattern[2]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.390 - Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B	No	—	No[1]	---
132-1 - Soil Dissipation	TEP	A,B	No	—	No[1]	---
133-3 - Dermal Exposure	TEP	A,B	No	—	No[1]	---
133-4 - Inhalation Exposure	TEP	A,B	No	—	No[1]	---
§158.440 - Spray Drift						
201-1 - Droplet Size Spectrum	TEP	A,B	No	—	No[1]	---
201-1 - Drift Field Evaluation	TEP	A,B	No	—	No[1]	---
Special Tests						

1/ This data requirement is not being imposed at this time because rotenone dose not meet the toxicity criteria of 40 CFR 158.390.

TABLE A
GENERIC DATA REQUIREMENTS FOR ROTENONE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.490 Wildlife and Aquatic Organisms						
Special Testing						
70-1 - Residue Monitoring-water	TEP	A,D	No		Reserved[1]	
Avian and Mammalian Testing						
71-1 - Acute Avian Oral Toxicity	TGAI	A,B,D, G,H	No		Yes	9 Months
71-2 - Avian Subacute Dietary Toxicity						
- Upland Game Bird, and	TGAI	A,B,D, G,H	No		Yes	9 Months
- Waterfowl	TGAI	A,B,D,H	No		Yes	9 Months
71-3 - Wild Mammal Toxicity	TGAI	A,B,D	No		No	
71-4 - Avian Reproduction						
- Upland Game Bird, and	TGAI	A,B,D	No		Yes[2]	24 Months
- Waterfowl		A,B,D	No		Yes[2]	24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR ROTENONE (cont.'d)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.490 Wildlife and Aquatic Organisms						
Aquatic Organism Testing						
71-5 - Simulated Field Testing	TEP	A,B,D				
- Mammals, and			No		No	
- Birds			No		No	
- Actual Field Testing	TEP	A,B,D	No		No	
- Mammals, and						
- Birds			No		No	
72-1 - Acute Toxicity to Freshwater Fishes						
- Coldwater Fish Species, and	TGAI	A,B,D, G,H	Partially	40098001	Yes[7]	9 Months
	TEP(5%WP)	[A,D][9]	Yes	See Footnote #5	No	
	Degradation Product	A,D	No		Yes[3]	9 Months
- Warmwater Fish Species	TGAI	A,B,D,G,H	Partially	40098001	Yes[7]	9 Months
	TEP(5%WP)	[A,D][9]	Yes	See Footnote #5	No	
	Degradation Product	A,D	No		Yes[3]	9 Months
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B,D, G,H	Partially	40063303	Yes[7]	9 Months
	TEP(5%WP)	[A,D][9]	Yes	00097842,40098001	No	
	Degradation Product	A,D	No		Yes[3]	9 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR ROTENONE (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.490 Wildlife and Aquatic Organisms						
Aquatic Organism Testing (cont'd)						
72-3 - Acute Toxicity to Estuarine and Marine Organisms						
- Fish	TGAI	A,D	No		Yes	12 Months
	TEP(5%WP)	[A,D][9]	Partially	40228402	Yes[6]	12 Months
	Degradation Product	A,D	No		Yes[3]	12 Months
- Mollusk	TGAI	A,D	No		Yes[4]	12 Months
	TEP (5%WP)	[A,D]	Partially	00108338, 40228402	Reserved	
	Degradation Product	A,D	No		Reserved	
- Shrimp	TGAI	A,D	No		Yes	12 Months
	TEP (5%WP)	[A,D][9]	Partially	40228402	Reserved[6]	
	Degradation Product	A,D	No		Yes	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR ROTENONE (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.490 Wildlife and Aquatic Organisms						
Aquatic Organism Testing (cont'd)						
72-4 - Fish Early Life Stage,						
- Freshwater Species	TGAI	A,D	Partially	40063303	Yes[7]	12 Months
	Degradation Product	A,D	No		Reserved[3]	
- Estuarine/Marine Species	TGAI	A,D	No		Reserved	
	Degradation Product	A,D	No		Reserved[3]	
72-4 - Aquatic Invertebrate Life Cycle						
- Freshwater Species	TGAI	A,D	Partially	40063303	Yes[7]	12 Months
	Degradation Product	A,D	No		Reserved[3]	
- Estuarine/Marine Species	TGAI	A,D	No		Reserved	
	Degradation Product	A,D	No		Reserved[3]	
72-5 - Fish - Life Cycle	TGAI	A,D	No		Yes	27 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR ROTENONE (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.490 Wildlife and Aquatic Organisms						
Aquatic Organism Testing (cont'd)						
72-6 - Aquatic Organism Accumulation	TEP	A,D				
	Degradation Product	A,D				
- Crustacean			No		Reserved3/	
- Fish			Yes		No	
- Insect Nymph			No		No	
- Mollusk			No		Reserved3/	
- Shrimp			No		Reserved3/	
72-7 - Simulated Field Testing - Aquatic Organisms	TEP	A,D	No		Reserved	
- Actual Field Testing - Aquatic Organisms	TEP	A,D	No		Yes8/	36 months Protocol: 6 months

TABLE A
GENERIC DATA REQUIREMENTS FOR ROTENONE (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.490 Wildlife and Aquatic Organisms						

Footnotes

1/ Residue monitoring studies are reserved pending the review results of environmental fate studies (i.e., degradation product identification and characterization). The Agency will notify the registrants if and when protocols and studies are due.

2/ Avian reproduction studies are required to support uses in which there are repeat applications.

3/ The 72-1, 72-2, and 72-3 acute degradation studies will require testing on the major degradate product, rotenolone. Other degradation product testing (72-4) and accummulation (72-6) requirements will be reserved pending the results of the initial acute degradation studies and environmental fate studies.

4/ The data derived from the estuarine mollusk acute studies shall also be extrapolated to freshwater mussels concerns for risk assessment purposes, particularly since listed endangered mussels are freshwater species. The TGAI test must be an oyster embryo larvae study.

5/ Due to multiple citations and limited space, the following citations for the TEP requirement are: 121873, 40063301, 89904, 61296, 90420, 90425, 90366, 90365, 90288, 89909, 89908, 89905, 89906, 90421, 90367, 121874, 121875, 121876, 121877, 121880, 121881, 121882, 121883, 121884, 121885, 121885, 121886, and 40094602.

6/ The need for additional data will be determined after completion of the review of data from EPA's Gulf Breeze Laboratory.

7/ Data submitted by the U.S. Fish and Wildlife Service are under review. The need for additional data will be determined when the review of these data is completed.

8/ An aquatic mesocosm study must be designed and executed with appropriate techniques to determine acute mortality and effects on invertebrate populations in landlocked aquatic environments following controlled fish kills and must identify and quantitate degradation product residues. A guidance document is available from the Agency, which outlines an acceptable approach to mesocosm studies.

9/ Required to support the piscicide and cranberry use patterns.

TABLE A
GENERIC DATA REQUIREMENTS FOR ROTENONE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.540 Plant Protection						
121-1 - Target Area Phytotoxicity	EP	A,B,D, G,H	No		No[1]/	
Nontarget Area Phytotoxicity						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI	A,B,D, G,H	No		No[1]/	
122-1 - Vegetative Vigor	TGAI	A,B,D, G,H	No		No[1]/	
122-2 - Aquatic Plant Growth	TGAI	A,D	No		Yes[2]/	9 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR ROTENONE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.540 Plant Protection (cont.)						
Nontarget Area Phytotoxicity						
TIER II						
123-1 -Seed Germination Seedling Emergence	TGAI	A,B,D, G,H	No		No[1]	
123-1- Vegitative Vigor	TGAI	A,B,D, G,H	No		N[1]	
123-2-Aquatic Plant Growth	TGAI	A,B,D, G,H	No		N[1]	

1/ These requirements are generally waived unless it is believed there is a phototoxicity problem.

2/ This data requirement is required to address possible impact concerns resulting from the aquatic food crop (cranberries) and the piscicide use patterns.

TABLE A
GENERIC DATA REQUIREMENTS FOR ROTENONE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Time Frame for Submission
§158.590 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honeybee acute contact LD_{50}	TGAI	A,B,H	YES	00036935 05001991	NO	
141-2 - Honeybee - toxicity of residues on foliage	TEP	A,B,H	NO		NO[1]	
141-5 - Field testing for pollinators	TEP	A,B,H	NO		NO[1]	

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[1] As data from the acute test indicate low toxicity, further testing is not required.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR ROTENONE MANUFACTURING-USE PRODUCTS.

Data Requirement	Composition[1]	Does EPA have data to satisfy this requirement?[2]	Bibliographic Citation[b]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
Part 158					
Subpart C-Product Chemistry					
Product Identity and Composition					
61-1. Product Identity and Disclosure of Ingredients	MP	No	N/A	Yes[3]	6 months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No	N/A	Yes[4]	6 months
61-3 - Discussion of Formation of Impurities	MP	No	N/A	Yes[5]	6 months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	MP	No	N/A	Yes[6]	12 months
62-2 - Certification of Ingredient Limits	MP	No	N/A	Yes[7]	12 months
62-3 - Analytical Methods to Verify Certified Limits	MP	No	N/A	Yes[8]	12 months
Physical and Chemical Characteristics					
63-2 - Color	MP	No	N/A	Yes[9]	6 months
63-3 - Physical State	MP	No	N/A	Yes[9]	6 months
63-4 - Odor	MP	No	N/A	Yes[9]	6 months
63-7 - Density, Bulk Density or Specific Gravity	MP	No	N/A	Yes[9]	6 months
63-12 - pH	MP	No	N/A	Yes[9,10]	6 months
62-14 - Oxidizing or Reducing Action	MP	No	N/A	Yes[9,11]	6 months
62-15 - Flammability	MP	No	N/A	Yes[9,12]	6 months
63-16 - Explodability	MP	No	N/A	Yes[9,13]	6 months
63-17 - Storage Stability	MP	No	N/A	Yes[9]	15 months
63-18 - Viscosity	MP	No	N/A	Yes[9,14]	6 months

(Continued, footnotes follow.)

TABLE B. (Continued).

Data Requirement	Composition[1]	Does EPA have data to satisfy this requirement?[2]	Bibliographic Citation[2]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
Part 158 Subpart C-Product Chemistry (cont.)					
63-19 -Miscibility	MP	No	N/A	Yes[9,15]	6 months
63-20 -Corrosion Characteristics	MP	No	N/A	Yes[9]	15 months
Other Requirements: 64-1 - Submittal of Samples	N/A	N/A	N/A	No	

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[1] Composition: MP = Manufacturing-Use Product.

[2] Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

[3] The chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredients, the following must also be provided: the product, common, and trade names; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned company code numbers.

[4] Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

[5] A detailed discussion of all impurities that are or may be present at $\geq 0.1\%$, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

TABLE B. (Continued).

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[6] Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation data (accuracy and precision) must be submitted for each analytical method used.

[7] Upper and lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity present at ≥0.1% (w/w) and each "toxicologically significant" impurity present at <0.1% (w/w) must be provided and certified. Also, an explanation of how each certified limit was established must be provided (e.g., sample analysis using validated analytical procedures, quantitative estimate based on amounts of ingredients used, etc.). Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certifications must be submitted on EPA Form 8570 Rev. 2-85.

[8] Analytical methods must be provided to determine the active ingredient, and each toxicologically significant impurity and intentionally added inert for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

[9] Physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, partition coefficient, pH, and stability) as required in 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

[10] Data required if the test substance is dispersible in water.

[11] Data required if the product contains an oxidizing or reducing agents.

[12] Data required if the product contains combustible liquids.

[13] Data required if the product is potentially explosive.

[14] Data required if the product is a liquid.

[15] Data required if the product is a liquid and is to be diluted with petroleum solvents.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ROTENONE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.340 - Toxicology						
ACUTE TESTING						
81-1 - Acute Oral Toxicity - Rat	MP	ALL	YES	00145496	NO	
81-2 - Acute Dermal Toxicity - Rabbit	MP	ALL	NO		YES	9 Months
81-3 - Acute Inhalation Toxicity - Rat	MP	ALL	NO		YES	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	ALL	NO		YES	9 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	ALL	NO		YES	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	ALL	NO		YES	9 Months

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label test. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA estab- lishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

SUMMARY-2

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely.
[40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40CFR 156.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv).

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to sue or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-7

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by . . . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units.
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage is given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all	
7E	Referral statement	All products where precautionary labeling appears on other than front panel	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§156.10 Labeling Requirements for Pesticides and Devices.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

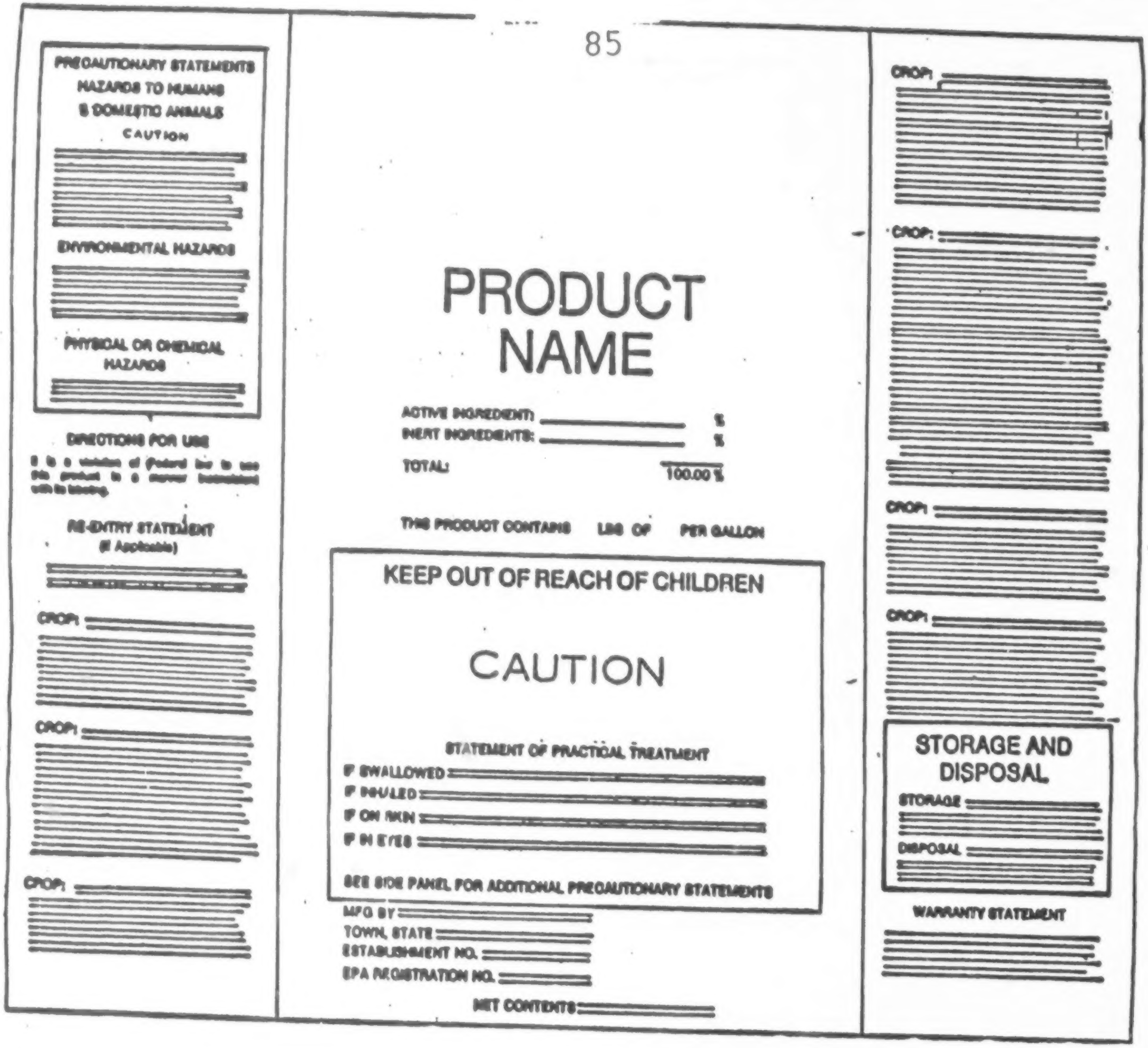
(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
& DOMESTIC ANIMALS
CAUTION

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

CROP:

CROP:

CROP:

PRODUCT
NAME

ACTIVE INGREDIENT: %
INERT INGREDIENTS: %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.

NET CONTENTS

CROP:

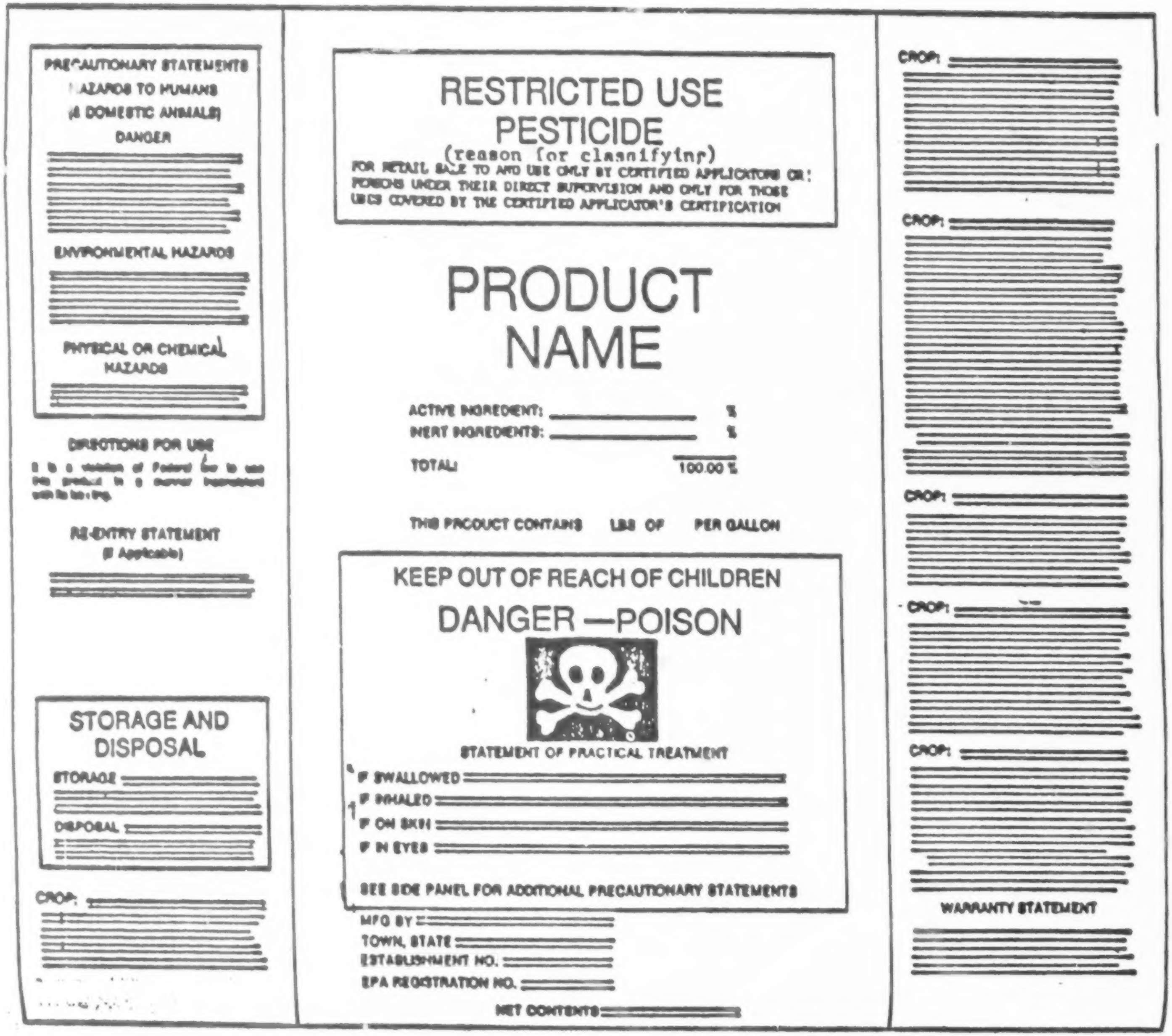
CROP:

CROP:

CROP:

STORAGE AND DISPOSAL
STORAGE
DISPOSAL

WARRANTY STATEMENT



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL
HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

STORAGE AND
DISPOSAL

STORAGE

DISPOSAL

CROP:

RESTRICTED USE
PESTICIDE
(reason for classifying)
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION

PRODUCT
NAME

ACTIVE INGREDIENT: %
INERT INGREDIENTS: %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN
DANGER —POISON

STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.
NET CONTENTS

CROP:

CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT

Chapter I--Environmental Protection Agency

§156.10 Labeling Requirements for Pesticides and Devices.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is

necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label or labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to §162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any Agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed;" and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"; and

(C) "Pollution approved."

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to §162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ***" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68 degrees F (20 degrees C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishment registration number. The producing establishment registration number preceded by the phrase "EPA Est.," of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups: those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

	Toxicity Categories			
Hazard Indicators	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "Poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "Keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of Label Front Panel in Square Inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity Category	Precautionary Statements by Toxicity Category	
	Oral, Inhalation, or Dermal Toxicity	Skin and Eye Local Effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel statement of practical treatment required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]	Avoid contact with skin, eyes, or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.]	[No precautionary statements required.]

(ii) Environmental hazards. Where a hazard exists to nontarget organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flashpoint	Required Text
(A) PRESSURIZED CONTAINERS	
Flashpoint at or below 20 degrees F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130 degrees F may cause bursting.
Flashpoint above 20 degrees F and not over 80 degrees F the flame extension is more than 18 inches long at a distance of 6 inches from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 degrees F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 degrees F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20 degrees	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20 degrees F and not over 80 degrees F	Flammable. Keep away from heat and open flame.
Above 80 degrees F and not over 150 degrees F	Do not use or store near heat or open flame.

(i) Directions for Use--(1) General requirements--(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) Placement of directions for use. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular"; and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) Exceptions to requirement for directions for use--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information, such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug, and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the heading "Directions for Use."

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in §162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of §162.10(j)([illegible]).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use," and reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in §162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 CF 28268, July 3, 1975; 40 FR 32329, August 1, 1975; 40 FR 38571, August 21, 1975, as amended at 43 FR 5786, February 9, 1978; amended at 53 FR 15952, May 4, 1988.

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1]/, dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1]/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. BIBLIOGRAPHY APPENDICES

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

    a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
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Citations Considered to be Part of the Data Base Supporting Registrations Under the Rotenone Standard

MRID	CITATION
00036935	Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1975) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. By University of California, Dept. of Entomology. ?: UC, Cooperative Extension. (Leaflet 2287; published study.)
00045126	Claborn, H.V.; Radeleff, R.D.; Bushland, R.C. (1960) Pesticide Residues in Meat and Milk: A Research Report. (U.S. Agricultural Research Service, Entomology Research Div. and Animal Disease and Parasite Research Div., unpublished study; CDL:093429-S)
00061296	McCann, J.A. (1969) Security Brand Fish-Tox: Toxicity to Bluegill: Test No. 145. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory; unpublished study; CDL:104469-A)
00072106	Hazleton Laboratories, Incorporated (1959?) Results of Tests on the Amount of Residue Remaining; Description of the Analytical Method: [Rotenone]. (Compilation; unpublished study including published data, received May 3, 1968 under 9F0766; CDL:091320-B)
00089904	Pitcher, F. (1972) [Prentox Cube Resins: Rainbow Trout (Salmo gairdneri)]: Test No. 491. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory, Fish Toxicity Laboratory; unpublished study; CDL:130277-A)
00089905	McCann, J.A. (1972) [Security Powdered Cube: Rainbow Trout (Salmo gairdneri)]: Test No. 472. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory, Fish Toxicity Laboratory; unpublished study; CDL:130278-A)
00089906	McCann, J.A. (1972) [Martin's Cube Powder: Rainbow Trout (Salmo gairdneri)]: Test No. 481. (U.S. Agricultural Research service, Animal Biology Laboratory, Fish Toxicity Laboratory; unpublished study; CDL:130279-A)
00089908	McCann, J.A. (1972) [Unico Rotenone Spray Powder: Rainbow Trout (Salmo gairdneri)]: Test No. 458. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory, Fish Toxicity Laboratory; unpublished study; CDL:130281-A)
00089909	McCann, J.A. (1972) [Pronoxfish Fish Toxicant: Bluegill (Lepomis macrochirus)]: Test No. 449. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory, Fish Toxicity Laboratory; unpublished study; CDL:130282-A)

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00090288	McCann, J.A. (1972) [Noxfish Fish Toxicant: Bluegill (Lepomis macrochirus)]: Test No. 438. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory, Fish Toxicity Laboratory; unpublished study; CDL:130283-A)
00090365	McCann, J.A. (1970) [Stephenson's 5% Cube Dust: Bluegill Lepomis macrochirus]: Test No. 295. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory, Fish Toxicity Laboratory; unpublished study; CDL:130290-A)
00090366	McCann, J.A. (1968) [Powdered Cube Rotenone: Bluegill (Lepomis macrochirus)]: Test No. 126. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory, Fish Toxicity Laboratory; unpublished study; CDL:130291-A)
00090367	McCann, J.A. (1970) [Unico Rotenone: Rainbow Trout (Salmo gairdneri)]: Test No. 248. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory, Fish Toxicity Laboratory; unpublished study; CDL:130292-A)
00090420	Pitcher, F. (1972) [Cube Powder Rotenone (Powder): Rainbow Trout (Salmo gairdneri)]: Test No. 506. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory; unpublished study; CDL:130295-A)
00090421	McCann, J.A.; Pitcher, F. (1972) [Pearson's 5% Rotenone: Rainbow Trout (Salmo gairdneri)]: Test No. 519. (U.S. Environmental Protection Agency, Pesticides Regulation Div., Animal Biology Laboratory; unpublished study; CDL:130296-A)
00090425	McCann, J.A.; Pitcher, F. (1972) [Pearson's 5% Rotenone: Bluegill (Lepomis macrochirus)]: Test No. 516. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory; unpublished study; CDL:130262-A)
00093702	Biotech Research Laboratories, Incorporated (1981) Analytical Studies for the Detection of Chromosomal Aberrations in Fruit Flies, Rats, Mice, and Horse Bean: Contract No. 14-16-0009-80-054. (For U.S. Fish and Wildlife Service, National Fishery Research Laboratory; unpublished study; CDL:246587-A)
00103047	Biotech Research Laboratories, Inc. (1982) Analytical Studies for the Detection of Chromosomal Aberrations in Fruit Flies, Rats, Mice, and Horse Bean: Contract No. 14-16-0009-80-054. Final rept. (U.S. Fish and Wildlife Service, National Fishery Research Laboratory; Unpublished study; CDL:247604-D)

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00121875 McCann, J. (1968) [Miller's Rotefive: Rainbow Trout]: Test No. 91. (Unpublished study received Jun 15, 1968 under unknown admin. no.; prepared by U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory, submitted by U.S. Environmental Protection Agency, Beltsville, MD; CDL:104497-A)

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00121877 McCann, J. (1968) [Noxfish: Bluegill]: Test No. 112. (Unpublished study received Sep 21, 1968 under unknown admin. no.; prepared by U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory, submitted by U.S. Environmental Protection Agency, Beltsville, MD; CDL:104499-A)

00121880 McCann, J. (1971) [Prentiss Cube Powder: Bluegill]: Test No. 354. (Unpublished study received Apr 24, 1971 under unknown admin. no.; prepared by U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory, submitted by U.S. Environmental Protection Agency, Beltsville, MD; CDL:128435-A)

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00121882	McCann, J; Pitcher, F. (1973) [Security Powdered Cube: Rainbow Trout]: Test No. 595. (Unpublished study received Jun 1, 1973 under 769-414; prepared by Pesticides Regulation Div., Animal Biology Laboratory, submitted by U.S. Environmental Protection Agency, Beltsville, MD; CDL:128486-A)
00121883	McCann, J.; Pitcher, F. (1972) [Pearson's 5% Rotenone: Bluegill]: Test No. 516. (Unpublished study received Nov 25, 1972 under 728-100; prepared by Pesticides Regulation Div., Animal Biology Laboratory, submitted by U.S. Environmental Protection Agency, Beltsville, MD; CDL:128570-A)
00121884	Pitcher, F. (1974) [Durham's 5% Rotenone: Rainbow Trout]: Test No. 677. (Unpublished study received Mar 19, 1974 under 430-29; prepared by Pesticides Regulation Div., Animal Biology Laboratory, submitted by U.S. Environmental Protection Agency, Beltsville, MD; CDL:129217-A)
00121885	Pitcher, F. (1974) [Unico Rotenone Spray Powder: Bluegill]: Test No. 668. (Unpublished study received Mar 13, 1974 under 1386-206; prepared by Pesticides Regulation Div., Animal Biology Laboratory, submitted by U.S. Environmental Protection Agency, Beltsville, MD; CDL:129218-A)
00121886	Pitcher, F. (1974) [Unico Rotenone Spray: Rainbow Trout]: Test No. 690. (Unpublished study received Jun 18, 1974 under 1386-206; prepared by Pesticides Regulation Div., Animal Biology Laboratory, submitted by U.S. Environmental Protection Agency, Beltsville, MD; CDL:132483-A)
00141273	Spare, W. (1984) Final Report: Anaerobic Aquatic Metabolism of :Radiolabeled: Rotenone: Project No. 82-E-076-AM. Unpublished study prepared by Biospherics, Inc. 19 p.
00141406	Ellis, H.; Unwin, S.; Cox, J.; et al. (1980) Subchronic Oral Dosing Study for Safety Evaluation of Rotenone Using Dogs: Final Report: MRI Project No. 4853-B. Unpublished study prepared by Midwest Research Institute. 64 p.

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00141408 Kehoe, D.; MacKenzie, K. (1983) Reproduction Study for Safety Evaluation of Rotenone Using Rats: Final Report: Study No. 81077. Unpublished study prepared by Hazleton Raltech, Inc. 732 p.

00144292 Brusick, D. (1981) Mutagenicity Studies on Rotenone: Final Report: LBI Project No. 22063. Unpublished study prepared by Litton Bionetics, Inc. 44 p.

00144294 MacKenzie, K. (1982) Teratology Study with Rotenone in Rats: Study No. 81178. Unpublished study prepared by Hazleton Raltech, Inc. 528 p.

00145496 Eiseman, J.; Thakur, A. (1984) General Metabolism Study for Safety Evaluation of Rotenone Using Rats: Project No. 419-137. Unpublished study prepared by Hazleton Laboratories, America, Inc. 311 p.

00146183 Gingerich, W.; Rach, J. (1985) Accumulation and Elimination of :6A-Carbon-14:-Rotenone by Bluegills: Final Report. Unpublished study prepared by U.S. Fish and Wildlife Service. 115 p.

00156739 Tisdel, M. (1985) Chronic Toxicity Study of Rotenone in Rats: Final Report: Study No. 6115-100. Unpublished study by prepared Hazleton Laboratories America, Inc. 1222 p.

00157850 Dawson, V. (1986) Adsorption-desorption of 6a-Carbon-14-Rotenone by Bottom Sediments: Final Report: ROT-84-988.02. Unpublished study prepared by National Fishery Research Laboratory, U.S. Fish and Wildlife Service. 144 p.

00157851 Gilderhus, P.; Dawson, V.; Allen, J. (1986) Persistence of Rotenone in Aquatic Environments at Different Temperatures: Final Report: Report No. ROT-83-988.02. Unpublished study prepared by National by National Fishery Research Laboratory, U.S. Fish and Wildlife Service. 99 p.

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05005830 Matthysse, J.G.; Lisk, D. (1968) Residues of diazinon, coumaphos, Ciodrin, methoxychlor, and rotenone in cow's milk from treatments similar to those used for ectoparasite and fly control on dairy cattle, with notes on safety of diazinon and Ciodrin to calves. Journal of Economic Entomology 61(5):1394-1398.

40063301 Bills, T.; Marking, L. (1986) Rotenone--Freshwater Fish LC50--Rainbow Trout and Bluegills: Laboratory Project ID; TOX 83-626.01B. Unpublished study prepared by U.S. Fish and Wildlife Service. 17 p.

40063303 Rach, J.; Bills, T.; Marking, L. (1986) Rotenone--Acute LC50 Freshwater Invertebrate--Daphnia: Rotenone Aquatic Invertebrate Life Cycle-Daphnia: Laboratory Project ID; TOX 83-626/01A. Unpublished study prepared by U.S. Fish and Wildlife Service. 26 p.

40094602 Johnson, W.; Finley, M. (1980) Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates: Resource Publication 137. US Fish and Wildlife Service, Washington, D.C. 106 p.

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40170502 Haworth, S. (1978) Salmonella/Mammalian-microsome Plate Incorporation Mutagenesis Assay (Rotenone): Laboratory Project ID: #019-563-165-1. Unpublished study prepared by EG&G Mason Research Institute. 26 p.

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40170506 SRI International (1987??) The Salmonella/Microsome Mutagenicity Test System (Rotenone). Unpublished compilation. 7 p.

40179801 Abdo, K. (1983) NTP Technical Report on the Toxicology and Carcinogenesis Studies on Rotenone...in F344/N Rats and B6C3F1 Mice (Feed Studies): Draft. Prepared by Battelle Columbus Laboratories for the National Toxicology Program. NIH Publication No. 86-2576. 186 p.

V. FORMS APPENDICES

EPA Form 8580-1

OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO

PRODUCT NAME

APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

Attach separate page with a list of the data requirements your company agrees to satisfy.

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

Attach list of data requirements

☐ 3. I enclose a completed "Certification of Attempt to Enter into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

OMB Approval No.
2070-005
Expires 11/30/89

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.____________________ Date____________________

Guidance Document for______________________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
Subpart C PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

EPA Form 8580-4

OMB Approval No.
2070-005
Expires 11/30/89

PRODUCT SPECIFIC DATA REPORT (cont'd)

EPA Reg. No.____________________________ Date____________________________________

Guidance Document for____

			I am complying with data requirements by		
Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
Subpart C PRODUCT CHEMISTRY (cont'd)					
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.340 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization,				
81-7	Acute Delayed neurotoxicity, hen				

EPA Form 8580-4 (cont'd)

EPA Form 8580-6

OMB Approval No. 2070-0057
Expires 11/30/89

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify __ALL__ four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ________________

Registrant's Name and Address: ____

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated ____________ concerning a requirement for submission of generic data on the active ingredient ______________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated __________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ________________________ and their registration number(s) is/are ______________ .

(4) My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product to one that is not registered and purchased.

(5) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(6) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ____________________________________
(Signature)

Dated: ____________________ ____________________________________
(Typed)

EPA Form 8580-3